



16.3 Case Report Forms

16.3.1 Case Report Forms for Deaths, Other Serious Adverse Events, and Withdrawals for Adverse Events

There were no deaths in this study. One subject experienced the SAE of subarachnoid hemorrhage after study completion and one subject was discontinued from the study due to an AE.

Patient CaseBook requested by User: "jbailey" in role: "View Only"

Trial: VLN, Version: MSC006
Site: 001-Mathew

Patient Type: Patient
Patient: 001018

Version Date: 02/22/2019
Date Generated:03/31/2019

Subject Information	
Subject Information	
Subject Number	001018
Informed Consent Date	17/JUL/2018 DD/MON/YYYY(EN)
Protocol Number	Original
Subject Type	Menthol Smoker
Randomization Number	001-006
Assigned Product	Menthol VLN
Re-Consent Date	
Protocol Amendment Number Re-consent	Informed Re-Consent Date
Amendment 2	31/JUL/2018 DD/MON/YYYY(EN)

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
Complete	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/29/2018 3:13:55 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/4/2018 1:28:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Complete	12/21/2018 1:09:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	1/10/2019 2:53:50 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	2/7/2019 3:45:32 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	2/8/2019 6:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/12/2019 2:52:11 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	2/18/2019 4:34:13 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	2/23/2019 3:42:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/24/2019 5:13:32 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Subject Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
6	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001006	False	Recording Error	8/29/2018 3:13:55 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001018	False	Recording Error	9/4/2018 1:28:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001018	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	

Informed Consent Date

							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
17/JUL/2018	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	

Protocol Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
ORIGINAL	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORIGINAL	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	

Subject Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
MENTHOL SMOKER	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MENTHOL SMOKER	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	

Randomization Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	
6	False	Transcription Error	12/21/2018 1:09:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001-006	False	Transcription Error	2/8/2019 6:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001-006	True	- Empty -	2/12/2019 2:52:11 PM CT	(b) (6)	CRA	001-Mathew	

Randomization Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	

Assigned Product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
MENTHOL VLN	False	Transcription Error	12/21/2018 1:09:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

MENTHOL VLN	True	- Empty -	1/10/2019 2:53:50 PM CT	(b) (6)	CRA	001-Mathew	
Active							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
YES	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YES	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	
Enrolled							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
YES	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YES	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	
Enroll Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
17/JUL/2018	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	
Dropped							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	
Registration Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	
Subject Initials							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	
Subject Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
6	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001006	False	- Empty -	8/29/2018 3:13:55 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001018	False	- Empty -	9/4/2018 1:28:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001018	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	
Country							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNITED STATES	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	
Protocol Amendment Number Re-consent							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
AMENDMENT 2	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMENDMENT 2	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	
Informed Re-Consent Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
31/JUL/2018	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	- Empty -	9/13/2018 6:08:12 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit Name	Screening
Visit Date	17/JUL/2018 DD/MON/YYYY(EN)
Visit Number	1
Was tobacco cessation information provided?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:16:14 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:52:10 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 10:22:09 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Screening	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Screening	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Visit Type							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:16:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 10:22:09 AM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:16:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 10:22:09 AM CT	(b) (6)	CRA	001-Mathew	

Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/23/2018 12:34:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:15:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:16:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 10:22:09 AM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Inclusion / Exclusion Criteria Not Met

Met All Eligibility Criteria? ☒ No ☒ Yes

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:34:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:24:53 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Met All Eligibility Criteria?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:34:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:24:53 PM CT	(b) (6)	CRA	001-Mathew	
Criterion Identifier							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:53 PM CT	(b) (6)	CRA	001-Mathew	
Criterion							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:53 PM CT	(b) (6)	CRA	001-Mathew	
Criterion Text 201-400 (Hidden)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:53 PM CT	(b) (6)	CRA	001-Mathew	
Criterion Text 401-600 (Hidden)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:53 PM CT	(b) (6)	CRA	001-Mathew	
Criterion Text 601-800 (Hidden)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:34:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:53 PM CT	(b) (6)	CRA	001-Mathew	
Inclusion/Exclusion Category							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/23/2018 12:34:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:53 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag used to create form only once.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	8/23/2018 12:34:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	10/15/2018 3:24:53 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		17/JUL/2018 DD/MON/YYYY(EN)		
Time of Measurements (24 Hour Clock)		11:48 HH:MM		
Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>	168	Height	cm	
<input type="checkbox"/>	78.9	Weight	kg	NCS CS
<input type="checkbox"/>	28	Body Mass Index	kg/m2	NCS CS
<input type="checkbox"/>	98.3	Temperature	F	NCS CS
<input type="checkbox"/>	71	Heart Rate	beats/min	NCS CS
<input type="checkbox"/>	14	Respiratory Rate	breaths/min	NCS CS
<input type="checkbox"/>	140	Systolic Blood Pressure	mmHg	NCS CS
<input type="checkbox"/>	100	Diastolic Blood Pressure	mmHg	NCS CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Incomplete	10/7/2018 10:10:02 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:06:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	10/15/2018 3:24:19 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	10/15/2018 3:24:49 PM CT	(b) (6)	CRA	001-Mathew
Complete	10/19/2018 10:29:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/19/2018 10:32:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	11/13/2018 2:14:05 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Monitored	11/27/2018 5:48:11 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Partial Monitored	12/18/2018 2:16:20 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:52:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 10:38:59 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Form: Vital Signs							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please add the original vital signs results and add an unscheduled events for the recheck.	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	UPDATED	10/19/2018 10:32:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Corrected.	11/27/2018 5:48:11 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Field							

Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Time of Measurements (24 Hour Clock)							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
11:48	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
11:48	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
168	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
168	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 10:10:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
NCS	False	Transcription Error	10/8/2018 6:06:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NCS	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
NCS	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:16:20 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 10:38:59 AM CT	(b) (6)	CRA	001-Mathew	
Not Done							2

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
78.9	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
78.9	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	

- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
28	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
28	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.3	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.3	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
77	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
77	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
77	False	- Empty -	10/15/2018 3:24:19 PM CT	(b) (6)	CRA	001-Mathew	
71	False	Transcription Error	10/19/2018 10:29:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
71	True	- Empty -	11/27/2018 5:48:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Unit							5

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

RESP	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
143	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
143	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
143	False	- Empty -	10/15/2018 3:24:19 PM CT	(b) (6)	CRA	001-Mathew	
140	False	Transcription Error	10/19/2018 10:29:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

140	True	- Empty -	11/27/2018 5:48:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
94	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
94	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
94	False	- Empty -	10/15/2018 3:24:19 PM CT	(b) (6)	CRA	001-Mathew	
100	False	Transcription Error	10/19/2018 10:29:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
100	False	(Diastolic blood pressure should be between 40 and 95 mmHg, inclusively.) CORRECT AS IS	10/19/2018 10:29:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
100	False	Data verified by site.	11/13/2018 2:14:05 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
100	True	- Empty -	11/27/2018 5:48:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	

Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:35:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:24:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Electrocardiogram

Was the ECG performed? ☒ No ☒ Yes

Date of ECG B 17/JUL/2018
DD/MON/YYYY(EN)

Time of ECG (24 hour clock) 11:30
HH:MM

Overall ECG Clinical Significance ☒ Normal ☒ Abnormal, Not Clinically Significant ☒ Abnormal, Clinically Significant

ECG Test Name	Test Results	Units
Heart Rate	69	Beats per Minute
RR	870	Millisecond
PR	122	Millisecond
QT	390	Millisecond
QRS	84	Millisecond
QTcF	409	Millisecond

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	8/28/2018 5:10:08 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:52:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the ECG performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
What was the planned time point of the measurement?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Screening	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Screening	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Date of ECG							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	(Date of ECG should be equal to or after the Screening visit date and 1 day prior to the Day -1 visit date.) correct as is	12/19/2018 1:52:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

17/JUL/2018	True	Correct as entered.	1/10/2019 2:57:05 PM CT		(b) (6)	CRA	001-Mathew	
Time of ECG (24 hour clock)								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
11:30	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
11:30	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew		
Overall ECG Clinical Significance								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NORMAL	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NORMAL	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew		
If Abnormal, specify								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew		
ECG Test Name								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
ECG MEAN HEART RATE	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
ECG MEAN HEART RATE	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew		
Test Results								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
69	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
69	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EGHRMN	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EGHRMN	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) RR DURATION	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) RR DURATION	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
870	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
870	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Units							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	monitored?						
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RRMEAN	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RRMEAN	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) PR DURATION	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) PR DURATION	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
122	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
122	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRMEAN	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRMEAN	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) QT DURATION	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) QT DURATION	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
390	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
390	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTMEAN	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTMEAN	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	

ECG Test Name								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
SUMMARY (MEAN) QRS DURATION	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
SUMMARY (MEAN) QRS DURATION	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew		
Test Results								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
84	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
84	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew		
Units								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
msec	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
msec	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
QRS DUR	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
QRS DUR	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew		
ECG Test Name								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
QTcF - Fridericia's Correction Formula	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		

QTcF - Fridericia's Correction Formula True - Empty - 1/10/2019 2:57:05 PM CT (b) (6) CRA 001-Mathew

Test Results 6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
409	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
409	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	

Units 6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	

Test Code 6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:36:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 2:57:05 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Tobacco/Nicotine Product Use History	
Not Done	<input type="checkbox"/>
Duration of Cigarette Use	18
Unit for Duration of Cigarette Use	Years
Typical Number of Cigarettes Smoked Per Day	17
Usual Brand	PALL MALL
Usual Brand Style	GREEN
Usual Brand Flavor	MENTHOL
Usual Brand Size	KING

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:38:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:17:55 PM CT	(b) (6)	CRA	001-Mathew
Complete	11/2/2018 1:52:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	11/6/2018 7:20:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	11/27/2018 5:56:50 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/4/2018 7:24:26 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/12/2018 9:37:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 2:56:19 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Form: Tobacco/Nicotine Product Use History							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	The UB Product Forms were not located in the subject binder. Please add.	11/27/2018 5:56:50 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	not done, deviation written	12/12/2018 9:37:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	N/A	The UB Product Forms are now present in the subject source binder.	1/10/2019 2:56:19 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:38:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:17:55 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:38:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:17:55 PM CT	(b) (6)	CRA	001-Mathew	
Duration of Cigarette Use							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18	False	- Empty -	8/23/2018 12:38:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18	True	- Empty -	10/15/2018 3:17:55 PM CT	(b) (6)	CRA	001-Mathew	
Unit for Duration of Cigarette Use							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YEARS	False	- Empty -	8/23/2018 12:38:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YEARS	True	- Empty -	10/15/2018 3:17:55 PM CT	(b) (6)	CRA	001-Mathew	
Typical Number of Cigarettes Smoked Per Day							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17	False	- Empty -	8/23/2018 12:38:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

17	True	- Empty -	10/15/2018 3:17:55 PM CT	(b) (6)	CRA	001-Mathew	
Usual Brand							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PALL MALL	False	- Empty -	8/23/2018 12:38:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PALL MALL	True	- Empty -	10/15/2018 3:17:55 PM CT	(b) (6)	CRA	001-Mathew	
Usual Brand Style							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MENTHOL	False	- Empty -	8/23/2018 12:38:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MENTHOL	True	- Empty -	10/15/2018 3:17:55 PM CT	(b) (6)	CRA	001-Mathew	
GREEN	False	Transcription Error	11/2/2018 1:52:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GREEN	True	- Empty -	1/10/2019 2:56:19 PM CT	(b) (6)	CRA	001-Mathew	
Usual Brand Flavor							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MENTHOL	False	- Empty -	8/23/2018 12:38:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MENTHOL	True	- Empty -	10/15/2018 3:17:55 PM CT	(b) (6)	CRA	001-Mathew	
Usual Brand Size							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
85MM	False	- Empty -	8/23/2018 12:38:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
85MM	True	- Empty -	10/15/2018 3:17:55 PM CT	(b) (6)	CRA	001-Mathew	
KING	False	Transcription Error	11/6/2018 7:20:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
KING	True	- Empty -	1/10/2019 2:56:19 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

VLN Product Trial +

Number of cigarettes smoked 2 +

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:38:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:15:34 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Number of cigarettes smoked							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	False	- Empty -	8/23/2018 12:38:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	10/15/2018 3:15:34 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Urine Cotinine Screen

Was the Urine Cotinine sample collected?

☒ No ☒ Yes

Date of Collection

17/JUL/2018
DD/MON/YYYY
(EN)

Is result positive for urine cotinine (greater than or equal to 500 ng/mL)?

☒ No ☒ Yes

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:38:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:18:43 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the Urine Cotinine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:38:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:18:43 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 12:38:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

17/JUL/2018	True	- Empty -	10/15/2018 3:18:43 PM CT	(b) (6)	CRA	001-Mathew	
Is result positive for urine cotinine (greater than or equal to 500 ng/mL)?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:38:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:18:43 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Medical History

Has the subject experienced any past and/or concomitant medical conditions, significant past medical history or past surgeries? ☒ No ☒ Yes

MH Number	Reported Term	Unknown Start Date	Onset Date	Ongoing?	End Date
1	ALLERGY TO PENICILLIN	<input type="checkbox"/>	(b) (6) DD/MON/YYYY (EN)	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes	
2	TUBAL LIGATION	<input type="checkbox"/>	UNK/NOV/2008 DD/MON/YYYY (EN)	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes	UNK/NOV/2008 DD/MON/YYYY (EN)
3	BROKEN ARM	<input type="checkbox"/>	UNK/UNK/1985 DD/MON/YYYY (EN)	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes	UNK/UNK/1985 DD/MON/YYYY (EN)
4	SURGERY TO INSERT PIN INTO BROKEN ARM FOR REPAIR	<input type="checkbox"/>	UNK/UNK/1985 DD/MON/YYYY (EN)	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes	UNK/UNK/1985 DD/MON/YYYY (EN)

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Has the subject experienced any past and/or concomitant medical conditions, significant past medical history or past surgeries? 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	

MH Number 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	

Reported Term 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALLERGY TO PENICILLIN	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALLERGY TO PENICILLIN	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	

Unknown Start Date 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/7/2019 3:23:08 PM CT	(b) (6) prod	TBMigration	001-Mathew	

Onset Date 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

(b) (6)	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
(b) (6)	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
MH Number							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
2	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
Reported Term							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
TUBAL LIGATION	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TUBAL LIGATION	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
Unknown Start Date							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/7/2019 3:23:08 PM CT	(b) (6) prod	TBMigration	001-Mathew	

Onset Date								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
UNK/NOV/2008	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
UNK/NOV/2008	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew		
Ongoing?								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
N	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
N	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew		
End Date								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
UNK/NOV/2008	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
UNK/NOV/2008	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew		
MH Number								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
3	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
3	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew		
Reported Term								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
BROKEN ARM	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
BROKEN ARM	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew		
Unknown Start Date								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	

- Empty -	False	- Empty -	2/7/2019 3:23:08 PM CT	(b) (6) prod	TBMigration	001-Mathew	
Onset Date							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/UNK/1985	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1985	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing?							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
End Date							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/UNK/1985	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1985	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
MH Number							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
4	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
Reported Term							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
SURGERY TO INSERT PIN INTO BROKEN ARM FOR REPAIR	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SURGERY TO INSERT PIN INTO BROKEN ARM FOR REPAIR	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
Unknown Start Date							4

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/7/2019 3:23:08 PM CT	(b) (6) prod	TBMigration	001-Mathew	
Onset Date							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/UNK/1985	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1985	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing?							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	
End Date							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/UNK/1985	False	- Empty -	8/23/2018 12:43:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1985	True	- Empty -	10/15/2018 3:16:53 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Serology (HIV, HBsAg, HCV)

Was the Serology sample collected? ☒ No ☒ Yes

Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:43:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:18:32 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the Serology sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:43:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:18:32 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 12:43:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/15/2018 3:18:32 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Pregnancy Test

Was the pregnancy test performed? ☒ No ☒ Yes
Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)
Test Type Serum
Pregnancy Test Result ☒ Negative ☒ Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/9/2018 1:00:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:18:50 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the pregnancy test performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	10/9/2018 1:00:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:18:50 PM CT	(b) (6)	CRA	001-Mathew	

If No, reason not performed

							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/9/2018 1:00:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:50 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	10/9/2018 1:00:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/15/2018 3:18:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SERUM	False	- Empty -	10/9/2018 1:00:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SERUM	True	- Empty -	10/15/2018 3:18:50 PM CT	(b) (6)	CRA	001-Mathew	
Pregnancy Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	10/9/2018 1:00:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/15/2018 3:18:50 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Physical Examination - Full

Was the Physical Examination performed?

☒ No ☒ Yes

Date of Examination

17/JUL/2018
DD/MON/YYYY(EN)

Body System	If Other, specify	Result	Specify if Abnormal or Not Done	Specify Clinical Significance if Abnormal
General Appearance		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
HEENT		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Thyroid (Endocrine)		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Heart		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Chest		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Lungs		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Abdomen		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Skin		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Neurological		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Extremities		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Back/Neck		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Lymph Nodes		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Musculoskeletal		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS

Oral Cavity	+	+	Normal	+	NCS	CS	+
Oropharynx	+	+	Normal	+	NCS	CS	+
Other	+	DENTITION	Normal	+	NCS	CS	+

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the Physical Examination performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not performed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	

Date of Examination								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
17/JUL/2018	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
17/JUL/2018	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew		

Body System								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
GENERAL APPEARANCE	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
GENERAL APPEARANCE	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew		

If Other, specify								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew		

Result								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew		

Specify if Abnormal or Not Done								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		

- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEENT	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEENT	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
THYROID (ENDOCRINE)	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
THYROID (ENDOCRINE)	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEART	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEART	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CHEST	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CHEST	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							5

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LUNGS	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LUNGS	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	

Specify if Abnormal or Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	

Specify Clinical Significance if Abnormal							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	

Body System							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ABDOMEN	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ABDOMEN	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	

If Other, specify							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	

Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SKIN	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SKIN	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEUROLOGICAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEUROLOGICAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EXTREMITIES	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EXTREMITIES	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							10
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BACK/NECK	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BACK/NECK	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							11

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LYMPH NODES	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LYMPH NODES	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	

Result							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MUSCULOSKELETAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MUSCULOSKELETAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL CAVITY	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL CAVITY	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OROPHARYNX	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OROPHARYNX	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Body System							16
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							16
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DENTITION	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DENTITION	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Result							16
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							16
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							16
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:44:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:18:12 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Demographics	
Date of Birth	(b) (6) DD/MON/YYYY(EN)
Gender	Female
Age	41
Reproductive Status	Surgically Sterile
Ethnicity	Not Hispanic or Latino
Race	White/Caucasian

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:49:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:16:16 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Date of Birth							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
(b) (6)	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
(b) (6)	True	- Empty -	10/15/2018 3:16:16 PM CT	(b) (6)	CRA	001-Mathew	
Gender							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

F	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/15/2018 3:16:16 PM CT	(b) (6)	CRA	001-Mathew	
Age							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
41	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
41	True	- Empty -	10/15/2018 3:16:16 PM CT	(b) (6)	CRA	001-Mathew	
Age Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YEARS	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YEARS	True	- Empty -	10/15/2018 3:16:16 PM CT	(b) (6)	CRA	001-Mathew	
Reproductive Status							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SURGICALLY STERILE	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SURGICALLY STERILE	True	- Empty -	10/15/2018 3:16:16 PM CT	(b) (6)	CRA	001-Mathew	
Ethnicity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT HISPANIC OR LATINO	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT HISPANIC OR LATINO	True	- Empty -	10/15/2018 3:16:16 PM CT	(b) (6)	CRA	001-Mathew	
Race							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

WHITE/CAUCASIAN	False	- Empty	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WHITE/CAUCASIAN	True	- Empty	10/15/2018 3:16:16 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:16:16 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Exhaled CO Measurement

Were exhaled CO measurements performed? ☒ No ☒ Yes

Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)

Exhaled CO measurement (ppm) 29

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:44:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:18:22 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Were exhaled CO measurements performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:44:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:18:22 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 12:44:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/15/2018 3:18:22 PM CT	(b) (6)	CRA	001-Mathew	
Exhaled CO measurement (ppm)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29	False	- Empty -	8/23/2018 12:44:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29	True	- Empty -	10/15/2018 3:18:22 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Date of Collection	17/JUL/2018 DD/MON/YYYY(EN)
Test Name	Result
Opiates	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Amphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cocaine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cannabinoids	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Alcohol	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Methamphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/7/2018 10:09:47 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:06:28 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the Urine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Result							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NEGATIVE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 12:45:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	Question value " updated to 'ALCOHOL' by VTS based on DataChange editId 2348.	10/7/2018 10:09:47 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ALCOHOL	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPHETAMINE	False	Question value " updated to 'METHAMPHETAMINE' by VTS based on DataChange, StateChange editId 2308.	10/7/2018 10:09:47 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPHETAMINE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NEGATIVE	False	- Empty -	10/8/2018 6:06:28 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPH	False	Question value " updated to 'METHAMPH' by VTS based on DataChange editId 2348.	10/7/2018 10:09:47 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPH	True	- Empty -	10/15/2018 3:18:38 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Chemistry

Accession Number 18389773S
 Date of Collection 17/JUL/2018
 DD/MON/YYYY(EN)
 Time of Collection 11:59
 HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Albumin	4.8	g/dL	3.9	5		Yes No Recheck				
Alkaline Phosphatase	63	U/L	37	115		Yes No Recheck				
Alanine Aminotransferase	23	U/L	10	67		Yes No Recheck				
Aspartate Aminotransferase	17	U/L	14	48		Yes No Recheck				
Bilirubin	.3	mg/dL	.2	1.6		Yes No Recheck				
Carbon Dioxide	28.8	mmol/L	24	33.2		Yes No Recheck				
Creatinine	.97	mg/dL	.5	.9	H	Yes No Recheck				
Glucose	86	mg/dL	73	105		Yes No Recheck				
Potassium	4.7	mEq/L	3.7	5.2		Yes No Recheck				
Protein	7.3	g/dL	6.3	8.1		Yes No Recheck				
Sodium	141	mEq/L	135	143		Yes No Recheck				
Urea Nitrogen	14	mg/dL	6	17		Yes No Recheck				
Uric Acid	5.2	mg/dL	2.3	5.9		Yes No Recheck				

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:27 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Category							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CHEM	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CHEM	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18389773S	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18389773S	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17/JUL/2018	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17/JUL/2018	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

11:59	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
11:59	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
ALB	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
ALB	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Albumin	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Albumin	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.8	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.9	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
ALP	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
ALP	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Alkaline Phosphatase	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Alkaline Phosphatase	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
63	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
63	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Units								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

U/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
U/L	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
37	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
37	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
115	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
115	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
ALT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
ALT	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Alanine Aminotransferase	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Alanine Aminotransferase	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
23	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
23	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	

Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
U/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
U/L	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
10	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
10	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
67	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
67	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
AST	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
AST	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Aspartate Aminotransferase	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Aspartate Aminotransferase	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
U/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
U/L	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
14	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
14	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
48	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
48	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 1								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 3								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
BILI	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
BILI	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

Bilirubin	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Bilirubin	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.3	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.2	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.6	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.6	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CO2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CO2	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	

Test Name								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Carbon Dioxide	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Carbon Dioxide	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
28.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
28.8	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Units								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
mmol/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
mmol/L	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
24	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
24	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
33.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
33.2	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CREAT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CREAT	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Creatinine	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Creatinine	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.97	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.97	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Units							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.9	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Flag							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
H	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
H	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
N	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
N	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
GLUC	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
GLUC	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Glucose	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Glucose	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
86	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
86	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
73	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
73	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
105	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
105	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
K	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
K	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Potassium	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Potassium	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.7	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.7	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mEq/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mEq/L	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

3.7	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.7	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.2	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PROT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PROT	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Protein	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Protein	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.3	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
6.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
6.3	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
8.1	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
8.1	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
SODIUM	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
SODIUM	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Sodium	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Sodium	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
141	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
141	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Units							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mEq/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mEq/L	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
135	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
135	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
143	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
143	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 3								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
UEAN	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
UEAN	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Urea Nitrogen	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Urea Nitrogen	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

14	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
14	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Units							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
6	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
6	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
URATE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
URATE	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Uric Acid	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Uric Acid	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	

Test Result								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
5.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
5.2	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Units								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
mg/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
mg/dL	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
2.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
2.3	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
5.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
5.9	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:30 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b)(6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b)(6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b)(6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b)(6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b)(6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b)(6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b)(6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Hematology

Accession Number 18389777B
 Date of Collection 17/JUL/2018
 DD/MON/YYYY(EN)
 Time of Collection 11:59
 HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Basophils	0.0	Thou/uL	0	.1		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Basophils/Leukocytes	.2	%	0	2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Eosinophils	.1	Thou/uL	0	.5		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Eosinophils/Leukocytes	1.3	%	.5	7.4		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Hematocrit	44.1	%	35.3	47		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Hemoglobin	14.7	g/dL	12	15.9		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Lymphocytes	2.3	Thou/uL	1.1	3.2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Lymphocytes/Leukocytes	27.8	%	15.8	45.8		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Monocytes	.4	Thou/uL	.3	.9		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Monocytes/Leukocytes	4.6	%	4.9	12.8	L	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Neutrophils	5.4	Thou/uL	1.6	7.7		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Neutrophils/Leukocytes	65.9	%	38.4	74.2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Platelets	266	Thou/uL	155	361		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Erythrocytes	4.64	Mil/uL	3.95	5.21		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Leukocytes	8.2	Thou/uL	3.7	11.5		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:27 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:15:52 PM CT	(b)(6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:36:34 PM CT	(b)(6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b)(6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
HEME	False	- Empty -	1/16/2019 1:46:30 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HEME	True	- Empty -	1/28/2019 4:36:34 PM CT	(b)(6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
18389777B	False	- Empty -	1/16/2019 1:46:30 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18389777B	True	- Empty -	1/28/2019 4:36:34 PM CT	(b)(6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
17/JUL/2018	False	- Empty -	1/16/2019 1:46:30 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17/JUL/2018	True	- Empty -	1/28/2019 4:36:34 PM CT	(b)(6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
11:59	False	- Empty -	1/16/2019 1:46:30 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

11:59	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
BASO	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
BASO	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Basophils	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Basophils	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
0.0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0.0	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

0	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.1	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.1	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
BASOLE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
BASOLE	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Basophils/Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Basophils/Leukocytes	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.2	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
2	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
EOS	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
EOS	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Eosinophils	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Eosinophils	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.1	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.1	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
EOSLE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
EOSLE	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Eosinophils/Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Eosinophils/Leukocytes	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.3	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.4	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.4	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HCT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HCT	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hematocrit	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hematocrit	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
44.1	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
44.1	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
35.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
35.3	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
47	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
47	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HGB	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HGB	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hemoglobin	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hemoglobin	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
14.7	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
14.7	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
15.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15.9	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
LYM	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
LYM	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Lymphocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Lymphocytes	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
2.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
2.3	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
1.1	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
1.1	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
3.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
3.2	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 1								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		

Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
LYMLE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
LYMLE	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Lymphocytes/Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Lymphocytes/Leukocytes	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
27.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
27.8	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit								8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
15.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
15.8	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
45.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
45.8	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 1								8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew		

Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
MONO	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
MONO	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Monocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Monocytes	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.4	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.4	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

Thou/uL	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.3	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.9	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
MONOLE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
MONOLE	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Monocytes/Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Monocytes/Leukocytes	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.6	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.6	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

%	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.9	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12.8	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
L	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
N	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
N	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEUT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEUT	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Neutrophils	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Neutrophils	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.4	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.4	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.6	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.6	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.7	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.7	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEUTLE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEUTLE	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Neutrophils/Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Neutrophils/Leukocytes	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
65.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
65.9	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
38.4	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
38.4	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
74.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
74.2	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PLAT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PLAT	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Platelets	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Platelets	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
266	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
266	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
155	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
155	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
361	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
361	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							13
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
RBC	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
RBC	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Erythrocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Erythrocytes	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.64	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.64	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							14
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Mil/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Mil/uL	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.95	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.95	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.21	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.21	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							14

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
WBC	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
WBC	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Leukocytes	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
8.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
8.2	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Units							15

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.7	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.7	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
11.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
11.5	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:15:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:34 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Urinalysis

Accession Number 18389780U
Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)
Time of Collection 11:18
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Ketones	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Leukocyte Esterase	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Nitrite	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Occult Blood	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
pH	6.5		5.0	8.0		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Specific Gravity	1.002		1.005	1.030	L	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urine Bilirubin	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urine Glucose	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urine Protein	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urobilinogen	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:27 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UA	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UA	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18389780U	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18389780U	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17/JUL/2018	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17/JUL/2018	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
11:18	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
11:18	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
KETONES	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
KETONES	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Ketones	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Ketones	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 4								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
LEUKASE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
LEUKASE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Leukocyte Esterase	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Leukocyte Esterase	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew		
Units								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
NEG, TRACE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	

NEG, TRACE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NITRITE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NITRITE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Nitrite	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Nitrite	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
OCCBLD	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
OCCBLD	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Occult Blood	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Occult Blood	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PH	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PH	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
pH	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
pH	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
6.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
6.5	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.0	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
8.0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
8.0	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
SPGRAV	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
SPGRAV	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Specific Gravity	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Specific Gravity	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.002	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.002	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.005	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.005	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.030	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.030	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
L	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
N	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
N	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UBILI	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UBILI	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Bilirubin	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Bilirubin	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Units							7

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
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- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UGLUC	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UGLUC	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Glucose	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Glucose	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UPROT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UPROT	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Protein	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Protein	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UROBIL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UROBIL	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urobilinogen	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urobilinogen	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 1							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:20 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Virology

Accession Number 18390167S
Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)
Time of Collection 11:59
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Hep B Virus Surface Antigen	NON- REACTIVE		NON- REACTIVE			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Recheck				
Hepatitis C Virus Antibody	NON- REACTIVE		NON- REACTIVE			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Recheck				
HIV Antibody	NON- REACTIVE		NON- REACTIVE			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:27 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:16:22 PM CT	(b)(6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:36:07 PM CT	(b)(6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b)(6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
VIROL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
VIROL	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18390167S	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18390167S	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17/JUL/2018	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17/JUL/2018	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
11:59	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
11:59	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HBSAG	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HBSAG	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hep B Virus Surface Antigen	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hep B Virus Surface Antigen	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NON-REACTIVE	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NON-REACTIVE	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HCAB	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HCAB	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hepatitis C Virus Antibody	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hepatitis C Virus Antibody	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NON-REACTIVE	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Units							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NON-REACTIVE	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HIVAB	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HIVAB	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HIV Antibody	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HIV Antibody	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NON-REACTIVE	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

NON-REACTIVE	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:07 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Urine Drug Screen

Accession Number 18389780U
Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)
Time of Collection 11:18
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Cotinine	DETECTED		DETECTED			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:27 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:16:12 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

UDS	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UDS	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18389780U	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18389780U	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17/JUL/2018	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17/JUL/2018	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
11:18	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
11:18	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
COTININE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
COTININE	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Cotinine	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Cotinine	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
DETECTED	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
DETECTED	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
DETECTED	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
DETECTED	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:36:24 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	Start of Week -1
Visit Date	26/JUL/2018 DD/MON/YYYY (EN)
Visit Number	2
Did the subject report any changes in medical history(ies) since the last visit?	<input type="radio"/> No <input type="radio"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="radio"/> No <input type="radio"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="radio"/> No <input type="radio"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:17:15 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:52:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 11:08:31 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Start of Week - 1	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Start of Week - 1	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:17:15 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:08:31 AM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/19/2018 1:52:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:08:31 AM CT	(b) (6)	CRA	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:16:08 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Start of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Vital Signs

Not Done

26/JUL/2018

07:41

DD/MON/YYYY(EN)

HH:MM

Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>	78.7	Weight	kg	NCS CS
<input type="checkbox"/>	98.4	Temperature	F	NCS CS
<input type="checkbox"/>	87	Heart Rate	beats/min	NCS CS
<input type="checkbox"/>	18	Respiratory Rate	breaths/min	NCS CS
<input type="checkbox"/>	144	Systolic Blood Pressure	mmHg	NCS CS
<input type="checkbox"/>	<div>B</div> 96 <div></div>	Diastolic Blood Pressure	mmHg	NCS CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	9/13/2018 6:13:07 PM CT	(b) (6)	CRA	001-Mathew
Complete	9/14/2018 11:02:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Monitored	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Incomplete	12/18/2018 2:17:21 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:52:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:00:00 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Form: Vital Signs

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please add the original VS values and create unscheduled visits for the rechecks.	9/13/2018 6:13:07 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	updated	9/14/2018 11:02:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Updated.	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	

Not Done

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	

Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	

Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	

Time of Measurements (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:41	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:41	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	

Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
78.7	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
78.7	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.4	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.4	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
93	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
87	False	Transcription Error	9/14/2018 11:02:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
87	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Unit							5
	Field						

Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							6
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

RESP	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
135	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
144	False	Transcription Error	9/14/2018 11:02:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
144	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
93	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
96	False	Transcription Error	9/14/2018 11:02:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
96	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
96	False	(Diastolic Blood Pressure should be between 40-95, inclusively.) correct as is	12/19/2018 1:52:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
96	True	Correct as entered.	1/10/2019 3:00:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:11:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:14:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NCS	False	Transcription Error	9/14/2018 11:02:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NCS	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
NCS	True	- Empty -	10/15/2018 3:25:39 PM CT	(b) (6)	CRA	001-Mathew
NCS	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Start of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Urine Cotinine Screen

Was the Urine Cotinine sample collected? ☒ No ☒ Yes
 Date of Collection 26/JUL/2018
 DD/MON/YYYY
 (EN)
 Is result positive for urine cotinine (greater than or equal to 500 ng/mL)? ☒ No ☒ Yes

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 9:11:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:10:51 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the Urine Cotinine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 9:11:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:10:51 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:11:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

26/JUL/2018	True	- Empty -	9/13/2018 6:10:51 PM CT	(b) (6)	CRA	001-Mathew	
Is result positive for urine cotinine (greater than or equal to 500 ng/mL)?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 9:11:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:10:51 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Start of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Pregnancy Test

Was the pregnancy test performed? ☒ No ☒ Yes
Date of Collection 26/JUL/2018 DD/MON/YYYY(EN)
Test Type Serum
Pregnancy Test Result ☒ Negative ☒ Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 9:12:52 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	9/13/2018 6:11:21 PM CT	(b) (6)	CRA	001-Mathew
Complete	9/14/2018 7:50:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	10/15/2018 3:20:24 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	11/13/2018 3:14:44 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/19/2018 1:52:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	1/10/2019 3:00:29 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/11/2019 3:33:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/11/2019 3:42:46 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the pregnancy test performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 9:12:52 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:11:21 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not performed							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:12:52 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:11:21 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:12:52 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	9/13/2018 6:11:21 PM CT	(b) (6)	CRA	001-Mathew	
Test Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	TEST TAKEN AS SERUM	8/24/2018 9:12:52 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	Per the source, this was a chemistry test. Please verify,	9/13/2018 6:11:21 PM CT	(b) (6)	CRA	001-Mathew	
URINE	False	there is a note attached stating the test was taken as serum	9/14/2018 7:50:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	- Empty -	10/15/2018 3:20:24 PM CT	(b) (6)	CRA	001-Mathew	
URINE	False	This will be corrected during the next CRF update.	11/13/2018 3:14:44 PM CT	(b) (6)	CRA	001-Mathew	
URINE	False	- Empty -	12/19/2018 1:52:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SERUM	False	Transcription Error	2/11/2019 3:33:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SERUM	True	- Empty -	2/11/2019 3:42:46 PM CT	(b) (6)	CRA	001-Mathew	
Pregnancy Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/24/2018 9:12:52 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:11:21 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Start of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Exhaled CO Measurement

Were exhaled CO measurements performed? ☒ No ☒ Yes

Date of Collection

26/JUL/2018
DD/MON/YYYY(EN)

Exhaled CO measurement (ppm)

36

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 9:13:12 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:17:06 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Were exhaled CO measurements performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 9:13:12 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:17:06 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:13:12 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	9/13/2018 6:17:06 PM CT	(b) (6)	CRA	001-Mathew	
Exhaled CO measurement (ppm)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
36	False	- Empty -	8/24/2018 9:13:12 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
36	True	- Empty -	9/13/2018 6:17:06 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Start of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Date of Collection	26/JUL/2018 DD/MON/YYYY(EN)
Test Name	Result
Opiates	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Amphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cocaine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cannabinoids	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Alcohol	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Methamphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	10/7/2018 10:14:13 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:06:55 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:14:16 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the Urine sample collected? 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	

Test Name 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	

Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	

Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	

Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	

Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

AMPHET	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NEGATIVE	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:09:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:13:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:10:45 PM CT	(b) (6)	CRA	001-Mathew	
ALCOHOL	False	Question value " updated to 'ALCOHOL' by VTS based on DataChange editId 2349.	10/7/2018 10:14:13 PM CT	(b) (6)	Setup Administrator	001-Mathew	

ALCOHOL	True	- Empty -	10/15/2018 3:14:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPHETAMINE	False	Question value " updated to 'METHAMPHETAMINE' by VTS based on DataChange, StateChange editId 2309.	10/7/2018 10:14:13 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPHETAMINE	True	- Empty -	10/15/2018 3:14:16 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NEGATIVE	False	- Empty -	10/8/2018 6:06:55 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/15/2018 3:14:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPH	False	Question value " updated to 'METHAMPH' by VTS based on DataChange editId 2349.	10/7/2018 10:14:13 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPH	True	- Empty -	10/15/2018 3:14:16 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: Start of Week -1
Visit Date: 26/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Urine Drug Screen

Accession Number 18393958U
Date of Collection 26/JUL/2018
DD/MON/YYYY(EN)
Time of Collection 07:14
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Cotinine	DETECTED	+	DETECTED	+	+	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck	+	+	+	+

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:27 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:16:47 PM CT	(b) (6)	Setup Administrator	001-Mathew
No Data	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Incomplete	2/11/2019 12:42:58 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	2/11/2019 12:49:25 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Category	Field						1
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Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UDS	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
UDS	False	- Empty -	2/11/2019 12:42:59 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
UDS	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18393958U	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
18393958U	False	- Empty -	2/11/2019 12:42:59 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
18393958U	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
26/JUL/2018	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
26/JUL/2018	False	- Empty -	2/11/2019 12:42:59 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
26/JUL/2018	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
07:14	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
07:14	False	- Empty -	2/11/2019 12:42:59 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
07:14	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:47 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	False	- Empty -	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:49:25 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
COTININE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
COTININE	False	- Empty -	2/11/2019 12:42:59 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
COTININE	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Cotinine	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
Cotinine	False	- Empty -	2/11/2019 12:42:59 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
Cotinine	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
DETECTED	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
DETECTED	False	- Empty -	2/11/2019 12:42:59 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
DETECTED	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:47 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:49:25 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
DETECTED	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
DETECTED	False	- Empty -	2/11/2019 12:42:59 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
DETECTED	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:47 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:49:25 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:47 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:49:25 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:47 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:20:28 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:49:25 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:59:49 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:47 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:20:28 AM CT	(b)(6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:49:25 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:59:49 PM CT	(b)(6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:47 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:20:28 AM CT	(b)(6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:49:25 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:59:49 PM CT	(b)(6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:47 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:20:28 AM CT	(b)(6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:49:25 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:59:49 PM CT	(b)(6)	CRA	001-Mathew	
Lab Comment 4							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:16:47 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:20:28 AM CT	(b)(6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:49:25 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:59:49 PM CT	(b)(6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	End of Week -1
Visit Date	01/AUG/2018 DD/MON/YYYY (EN)
Visit Number	3
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:17:30 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:53:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 11:08:35 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Week - 1	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Week - 1	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:17:30 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:08:35 AM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/19/2018 1:53:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:08:35 AM CT	(b) (6)	CRA	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:16:19 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Randomization	
Randomization Date	01/AUG/2018 DD/MON/YYYY(EN)
Assigned Product	Menthol VLN

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	12/18/2018 2:17:30 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/21/2018 1:09:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 2:53:58 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Randomization Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:17:30 PM CT	(b) (6)	Setup Administrator	001-Mathew	
01/AUG/2018	False	- Empty -	12/21/2018 1:09:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	1/10/2019 2:53:58 PM CT	(b) (6)	CRA	001-Mathew	
Assigned Product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:17:30 PM CT	(b) (6)	Setup Administrator	001-Mathew	
MENTHOL VLN	False	- Empty -	12/21/2018 1:09:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MENTHOL VLN	True	- Empty -	1/10/2019 2:53:58 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: End of Week -1
Visit Date: 01/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

24-Hour Urine Collection

Planned Timepoint	Was the sample collected?	If No, reason not collected	Collection Start Date	Collection Start Time (24 Hour Clock)	Collection Stop Date	Collection End Time (24 Hour Clock)	Total Weight (g)	Was any void in this 24 hour period lost or discarded?	Comment for lost or discarded sample
EOW -1	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes		31/JUL/2018 DD/MON/YYYY (EN)	19:07 HH:MM	01/AUG/2018 DD/MON/YYYY (EN)	19:03 HH:MM	1721	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/26/2018 12:00:13 PM CT	[REDACTED]	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/26/2018 12:02:33 PM CT	[REDACTED]	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:18:12 PM CT	[REDACTED]	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	[REDACTED]	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	[REDACTED]	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Planned Timepoint							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	[REDACTED]	Clinical Research Coordinator (CRC)	001-Mathew	
EOW -1	False	- Empty -	8/26/2018 12:02:33 PM CT	[REDACTED]	Clinical Research Coordinator (CRC)	001-Mathew	
EOW -1	True	- Empty -	9/13/2018 6:18:12 PM CT	[REDACTED]	CRA	001-Mathew	
Was the sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/26/2018 12:02:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:18:12 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not collected							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:02:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Collection Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	False	(This item is invalid.) CORRECT AS IS	8/26/2018 12:02:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	Confirmed per source.	9/13/2018 6:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Collection Start Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:07	False	(Collection Start Time should be 07:00 (+/- 30 minutes).) CORRECT AS IS	8/26/2018 12:02:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:07	True	Confirmed per source.	9/13/2018 6:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Collection Stop Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 12:02:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	9/13/2018 6:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Collection End Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:03	False	(Collection Start Time should be 07:00 (+/- 30 minutes).) CORRECT AS IS	8/26/2018 12:02:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:03	True	Confirmed per source.	9/13/2018 6:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Total Weight (g)							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1721	False	- Empty -	8/26/2018 12:02:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1721	True	- Empty -	9/13/2018 6:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Was any void in this 24 hour period lost or discarded?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/26/2018 12:02:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:18:12 PM CT	(b) (6)	CRA	001-Mathew	
Comment for lost or discarded sample							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:02:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:18:12 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		<div>31/JUL/2018</div> <div>DD/MON/YYYY(EN)</div>		
Time of Measurements (24 Hour Clock)		<div>16:44</div> <div>HH:MM</div>		
Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>	98.5	Temperature	F	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	93	Heart Rate	beats/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	16	Respiratory Rate	breaths/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	145	Systolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	91	Diastolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew
Monitored	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	False	(Date of Measurements should be equal to the visit date.) correct as is	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	Confirmed per source.	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	

Time of Measurements (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:44	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:44	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

cm	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
	Field						

Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

BMI	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.5	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.5	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
93	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
93	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	

Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	

Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	

Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
145	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
145	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
91	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
91	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:48:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:13:43 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Puffing Topography

Not Done

01/AUG/2018
DD/MON/YYYY(EN)

Was topography data collected? ☒ No ☒ Yes

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	1/10/2019 1:06:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:01:30 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	False	- Empty -	1/10/2019 1:06:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:30 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	1/10/2019 1:06:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	1/10/2019 3:01:30 PM CT	(b) (6)	CRA	001-Mathew	

Was topography data collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	1/10/2019 1:06:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	1/10/2019 3:01:30 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: End of Week -1
Visit Date: 01/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Product Return

Product Name Menthol UB
 If Usual Brand, Specify PALL MALL
 Date Returned 31/JUL/2018
 DD/MON/YYYY(EN)
 Cigarette butts returned 85
 Did the subject consume any tobacco products other than the cigarettes reported in the e-Diary?
☒ No ☒ Yes
 If yes, please indicate when A Few Times
 If yes, estimate amount 2
 Is there any additional information to provide about the difference between reported cigarette use and number of cigarettes and butts returned?
☒ No ☒ Yes
 Specify additional information 8 BUTTS NOT ACCOUNTED FOR

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew
Complete	10/11/2018 2:13:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/16/2018 7:52:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/13/2018 3:15:15 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/6/2018 8:08:11 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Product Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MENTHOL UB	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MENTHOL UB	True	- Empty -	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	
If Usual Brand, Specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PALL MALL	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PALL MALL	True	- Empty -	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	
Date Returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	- Empty -	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	
Number of cigarettes returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
0	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
0	True	- Empty -	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	
Cigarette butts returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
85	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
85	True	- Empty -	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	
Number of Non-VLN butts returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	

Did the subject consume any tobacco products other than the cigarettes reported in the e-Diary?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	

If yes, please indicate when							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONCE	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONCE	False	Please clarify where this is located on the butt return form.	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	
A FEW TIMES	False	Transcription Error	10/11/2018 2:13:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
A FEW TIMES	False	per email	10/16/2018 7:52:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
A FEW TIMES	True	Clarified.	11/13/2018 3:15:15 PM CT	(b) (6)	CRA	001-Mathew	

If yes, estimate amount							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	

Is there any additional information to provide about the difference between reported cigarette use and number of cigarettes and butts returned?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	
Specify additional information							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
8 BUTTS NOT ACCOUNTED FOR	False	- Empty -	8/29/2018 1:42:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
8 BUTTS NOT ACCOUNTED FOR	True	- Empty -	9/13/2018 6:15:48 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Product Dispensed	
Product Name	Menthol VLN
If Usual Brand, Specify	
Date Dispensed	01/AUG/2018 DD/MON/YYYY(EN)
Number of cigarettes dispensed	360

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/26/2018 12:02:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:18:29 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Product Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MENTHOL VLN	False	- Empty -	8/26/2018 12:02:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MENTHOL VLN	True	- Empty -	9/13/2018 6:18:29 PM CT	(b) (6)	CRA	001-Mathew	
If Usual Brand, Specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:02:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:18:29 PM CT	(b) (6)	CRA	001-Mathew	

Date Dispensed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 12:02:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	9/13/2018 6:18:29 PM CT	(b) (6)	CRA	001-Mathew	
Number of cigarettes dispensed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
360	False	- Empty -	8/26/2018 12:02:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
360	True	- Empty -	9/13/2018 6:18:29 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Pregnancy Test	
Was the pregnancy test performed?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
Date of Collection	<input checked="" type="text"/> 31/JUL/2018 DD/MON/YYYY(EN)
Test Type	Urine
Pregnancy Test Result	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/27/2018 9:48:59 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:12:05 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	11/27/2018 5:57:12 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/19/2018 1:53:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:00:41 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Was the pregnancy test performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/27/2018 9:48:59 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:12:05 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not performed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/27/2018 9:48:59 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:12:05 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	False	(Date should be equal to the visit date.) correct as is	8/27/2018 9:48:59 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	Confirmed per source.	9/13/2018 6:12:05 PM CT	(b) (6)	CRA	001-Mathew	
Test Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	- Empty -	8/27/2018 9:48:59 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	True	- Empty -	9/13/2018 6:12:05 PM CT	(b) (6)	CRA	001-Mathew	
URINE	False	- Empty -	11/27/2018 5:57:12 PM CT	(b) (6)	CRA	001-Mathew	
URINE	True	- Empty -	1/10/2019 3:00:41 PM CT	(b) (6)	CRA	001-Mathew	
Pregnancy Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 12:45:52 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/27/2018 9:48:59 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:12:05 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Plasma/Blood Sampling				
Not Done	If Not Done, specify	Assay	Collection Date	Collection Time
<input type="checkbox"/>		Cotinine	01/AUG/2018 DD/MON/YYYY(EN)	13:09 HH:MM
<input type="checkbox"/>		COHb	01/AUG/2018 DD/MON/YYYY(EN)	13:07 HH:MM
<input type="checkbox"/>		Nicotine	02/AUG/2018 DD/MON/YYYY(EN)	07:57 HH:MM

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/11/2019 1:47:50 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/12/2019 4:28:56 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Not Done							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:47:50 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
If Not Done, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
Assay							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COTININE	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COTININE	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
Collection Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:09	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:09	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
If Not Done, specify							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
Assay							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COHB	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COHB	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
Collection Date							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							2

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:07	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:07	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
If Not Done, specify							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
Assay							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NICOTINE	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NICOTINE	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
Collection Date							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	

02/AUG/2018	False	Transcription Error	2/11/2019 1:47:50 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/AUG/2018	True	- Empty -	2/12/2019 4:28:56 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:09	False	- Empty -	8/26/2018 12:03:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:09	True	- Empty -	9/13/2018 6:16:39 PM CT	(b) (6)	CRA	001-Mathew	
07:57	False	Transcription Error	2/11/2019 1:47:50 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:57	True	- Empty -	2/12/2019 4:28:56 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
Date of Collection	31/JUL/2018 DD/MON/YYYY(EN)
Test Name	Result
Opiates	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive
Amphetamine	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive
Cocaine	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive
Cannabinoids	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive
Alcohol	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive
Methamphetamine	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	10/7/2018 10:25:15 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:09:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:14:20 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the Urine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	False	(Date of Drug Screen should be equal to the visit date.) correct as is	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	Confirmed per source.	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

OPIATES	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

AMPHET	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 12:00:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:49:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:11:48 PM CT	(b) (6)	CRA	001-Mathew	

ALCOHOL	False	Question value " updated to 'ALCOHOL' by VTS based on DataChange editId 2344.	10/7/2018 10:25:15 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ALCOHOL	True	- Empty -	10/15/2018 3:14:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPHETAMINE	False	Question value " updated to 'METHAMPHETAMINE' by VTS based on DataChange, StateChange editId 2304.	10/7/2018 10:25:15 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPHETAMINE	True	- Empty -	10/15/2018 3:14:20 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NEGATIVE	False	- Empty -	10/8/2018 6:09:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/15/2018 3:14:20 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPH	False	Question value " updated to 'METHAMPH' by VTS based on DataChange editId 2344.	10/7/2018 10:25:15 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPH	True	- Empty -	10/15/2018 3:14:20 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit	
Visit Not Done	<input type="checkbox"/>
Reason Not Done	
Visit Name	
Visit Date	
Visit Number	
Was tobacco cessation information provided?	<input type="radio"/> No <input type="radio"/> Yes
Please specify if not done	
Visit Type	<input type="radio"/> End of Study <input type="radio"/> Early Termination
Expected Visit Date	
Earliest Expected Visit Date	
Latest Expected Visit Date	
Planned Study Day of Visit	
Upcoming Visit Offset	
Visit Caption	
Did the subject report any changes in medical history(ies) since the last visit?	<input type="radio"/> No <input type="radio"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="radio"/> No <input type="radio"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="radio"/> No <input type="radio"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
No Data Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Reason Not Done							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit	
Visit Not Done	<input type="checkbox"/>
Reason Not Done	
Visit Name	
Visit Date	
Visit Number	
Was tobacco cessation information provided?	<input type="radio"/> No <input type="radio"/> Yes
Please specify if not done	
Visit Type	<input type="radio"/> End of Study <input type="radio"/> Early Termination
Expected Visit Date	
Earliest Expected Visit Date	
Latest Expected Visit Date	
Planned Study Day of Visit	
Upcoming Visit Offset	
Visit Caption	
Did the subject report any changes in medical history(ies) since the last visit?	<input type="radio"/> No <input type="radio"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="radio"/> No <input type="radio"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="radio"/> No <input type="radio"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
No Data Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Reason Not Done							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit	
Visit Not Done	<input type="checkbox"/>
Reason Not Done	
Visit Name	
Visit Date	
Visit Number	
Was tobacco cessation information provided?	<input type="radio"/> No <input type="radio"/> Yes
Please specify if not done	
Visit Type	<input type="radio"/> End of Study <input type="radio"/> Early Termination
Expected Visit Date	
Earliest Expected Visit Date	
Latest Expected Visit Date	
Planned Study Day of Visit	
Upcoming Visit Offset	
Visit Caption	
Did the subject report any changes in medical history(ies) since the last visit?	<input type="radio"/> No <input type="radio"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="radio"/> No <input type="radio"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="radio"/> No <input type="radio"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
No Data Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Reason Not Done							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	End of Study
Visit Date	15/AUG/2018 DD/MON/YYYY(EN)
Was tobacco cessation information provided?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
Please specify if not done	TOBACCO CESSATION INFORMATION NOT PROVIDED TO SUBJECT
Visit Type	<input checked="" type="radio"/> End of Study <input checked="" type="radio"/> Early Termination
Did the subject report any changes in medical history(ies) since the last visit?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/16/2018 10:51:56 AM CT	(b) (6)	CRA	001-Mathew
Complete	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/4/2018 8:18:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/12/2018 7:50:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/12/2018 10:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	1/10/2019 11:08:39 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	1/10/2019 11:11:18 AM CT	(b) (6)	CRA	001-Mathew
Monitored	1/16/2019 12:04:38 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Form: Visit							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	N/A	Please complete.	10/16/2018 10:51:56 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	completed	12/4/2018 8:18:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Completed.	1/16/2019 12:04:38 PM CT	(b) (6)	CRA	001-Mathew	
Group: Visit							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please update the drop/replace report for the reasons for dropping from the study.	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	report updated	12/12/2018 7:50:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Updated.	1/16/2019 12:04:38 PM CT	(b) (6)	CRA	001-Mathew	
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Study	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Study	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Please add this as a protocol deviation.	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
N	False	DEVIATION WRITTEN	12/12/2018 10:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	Completed.	1/16/2019 12:04:38 PM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT PROVIDED TO SUBJECT	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT PROVIDED TO SUBJECT	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Early Termination	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Early Termination	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	

Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	

Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	

Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	

Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	

Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	

Visit Caption							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	12/4/2018 7:26:39 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Study **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 15/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Physical Examination - Symptom-driven	
Did subject report any symptoms?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
If Yes, specify	NAUSEA, CONSTIPATION, PAIN
Was the Physical Examination performed?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
Date of Examination	15/AUG/2018 DD/MON/YYYY(EN)
Were there any abnormal findings?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	12/4/2018 7:19:35 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/12/2018 10:56:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	1/10/2019 3:02:18 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/13/2019 8:21:43 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Did subject report any symptoms?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Please change to yes per the source.	12/4/2018 7:19:35 PM CT	(b) (6)	CRA	001-Mathew	
N	False	Transcription Error	12/12/2018 10:56:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	updated	2/13/2019 8:21:43 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Transcription Error	2/13/2019 8:21:43 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	Completed.	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew	
If Yes, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA, CONSTIPATION, PAIN	False	Transcription Error	2/13/2019 8:21:43 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA, CONSTIPATION, PAIN	True	- Empty -	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew	
Was the Physical Examination performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Transcription Error	2/13/2019 8:21:43 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew	
If No, reason not performed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	2/13/2019 8:21:43 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew	
Date of Examination							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	Transcription Error	2/13/2019 8:21:43 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	- Empty -	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew	
Were there any abnormal findings?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Transcription Error	2/13/2019 8:21:43 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew	
Body System							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew	
Specify Abnormal Findings							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:59:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 10:27:56 AM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Study **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 15/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		15/AUG/2018 DD/MON/YYYY(EN)		
Time of Measurements (24 Hour Clock)		20:10 HH:MM		
Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>				<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	98.3	Temperature	F	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	96	Heart Rate	beats/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	14	Respiratory Rate	breaths/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	132	Systolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	85	Diastolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	(Date of Measurements should be equal to the visit date.) CORRECT AS IS	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	Correct as entered.	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	

Time of Measurements (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:10	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:10	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	

Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	

Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

cm	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Unit							3

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.3	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.3	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

TEMP	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
96	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
96	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
132	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

132	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
85	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
85	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:00:11 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:23:50 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: End of Study
Visit Date: 15/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Electrocardiogram

Was the ECG performed? ☒ No ☒ Yes

Date of ECG ☒ 15/AUG/2018
DD/MON/YYYY(EN)

Time of ECG (24 hour clock) 20:22
HH:MM

Overall ECG Clinical Significance ☒ Normal ☒ Abnormal, Not Clinically Significant ☒ Abnormal, Clinically Significant

ECG Test Name	Test Results	Units
Heart Rate	92	Beats per Minute
RR	650	Millisecond
PR	<input checked="" type="radio"/> 118	Millisecond
QT	354	Millisecond
QRS	84	Millisecond
QTcF	408	Millisecond

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the ECG performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
What was the planned time point of the measurement?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Study	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Study	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Date of ECG							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	(Date of ECG should be on the same day as the visit date.) correct as is	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	Correct as entered.	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Time of ECG (24 hour clock)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:22	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:22	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Overall ECG Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
If Abnormal, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ECG MEAN HEART RATE	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ECG MEAN HEART RATE	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
92	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
92	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	

Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EGHRMN	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EGHRMN	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) RR DURATION	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) RR DURATION	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
650	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
650	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Units							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

msec	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RRMEAN	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RRMEAN	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) PR DURATION	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) PR DURATION	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
118	False	(PR Interval should be between 120-200 msec (inclusive).) correct as is	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
118	True	Correct as entered.	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	monitored?							
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
PRMEAN	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
PRMEAN	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew		
ECG Test Name								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
SUMMARY (MEAN) QT DURATION	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
SUMMARY (MEAN) QT DURATION	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew		
Test Results								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
354	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
354	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew		
Units								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
msec	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
msec	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
QTMEAN	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
QTMEAN	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew		
ECG Test Name								5

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) QRS DURATION	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) QRS DURATION	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
84	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
84	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QRS DUR	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QRS DUR	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTcF - Fridericia's Correction Formula	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTcF - Fridericia's Correction Formula	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	

Test Results							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
408	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
408	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:14:39 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:15:54 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Study **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 15/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Date of Collection	15/AUG/2018 DD/MON/YYYY(EN)
Test Name	Result
Opiates	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Amphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cocaine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cannabinoids	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Alcohol	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Methamphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the Urine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	(Date of Drug Screen should be equal to the visit date.) CORRECT AS IS	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	Correct as entered.	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	

Result							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	

Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	

Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	

Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NEGATIVE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

METHAMPHETAMINE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
METHAMPHETAMINE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
METHAMPH	False	- Empty -	12/4/2018 8:02:48 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
METHAMPH	True	- Empty -	12/4/2018 7:23:16 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Study **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 15/AUG/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Subject Disposition

Did the subject complete the study? ☒ No ☒ Yes
If No, reason for discontinuation Adverse Event
Primary Adverse Event Term 8-ANXIETY
Date of Completion or Discontinuation 15/AUG/2018
DD/MON/YYYY(EN)

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/4/2018 8:01:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:22:18 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Did the subject complete the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	12/4/2018 8:01:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:22:18 PM CT	(b) (6)	CRA	001-Mathew	

If No, reason for discontinuation							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	12/4/2018 8:01:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	12/4/2018 7:22:18 PM CT	(b) (6)	CRA	001-Mathew	

If Other, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:01:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:22:18 PM CT	(b) (6)	CRA	001-Mathew	

Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
8- ANXIETY	False	- Empty -	12/4/2018 8:01:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
8- ANXIETY	True	- Empty -	12/4/2018 7:22:18 PM CT	(b) (6)	CRA	001-Mathew	

If Non-compliance with Study Procedures, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:01:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:22:18 PM CT	(b) (6)	CRA	001-Mathew	

If Physician Decision, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:01:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:22:18 PM CT	(b) (6)	CRA	001-Mathew	

If Withdrawal by Subject, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	12/4/2018 8:01:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:22:18 PM CT	(b) (6)	CRA	001-Mathew	
Date of Completion or Discontinuation							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/4/2018 7:58:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	- Empty -	12/4/2018 8:01:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	- Empty -	12/4/2018 7:22:18 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: End of Study
Visit Date: 15/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Chemistry

Accession Number 18405904S
Date of Collection 15/AUG/2018
DD/MON/YYYY(EN)
Time of Collection 19:58
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Albumin	5.0	g/dL	3.9	5		Yes No Recheck				
Alkaline Phosphatase	68	U/L	37	115		Yes No Recheck				
Alanine Aminotransferase	23	U/L	10	67		Yes No Recheck				
Aspartate Aminotransferase	20	U/L	14	48		Yes No Recheck				
Bilirubin	.3	mg/dL	.2	1.6		Yes No Recheck				
Carbon Dioxide	26.6	mmol/L	24	33.2		Yes No Recheck				
Creatinine	.99	mg/dL	.5	.9	H	Yes No Recheck				
Glucose	100	mg/dL	73	105		Yes No Recheck				
Potassium	4.5	mEq/L	3.7	5.2		Yes No Recheck				
Protein	7.8	g/dL	6.3	8.1		Yes No Recheck				
Sodium	143	mEq/L	135	143		Yes No Recheck				
Urea Nitrogen	17	mg/dL	6	17		Yes No Recheck				
Uric Acid	5.1	mg/dL	2.3	5.9		Yes No Recheck				

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:27 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Category							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CHEM	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CHEM	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18405904S	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18405904S	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
15/AUG/2018	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15/AUG/2018	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

19:58	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
19:58	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
ALB	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
ALB	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Albumin	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Albumin	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.0	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.9	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
ALP	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
ALP	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Alkaline Phosphatase	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Alkaline Phosphatase	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
68	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
68	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Units								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

U/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
U/L	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
37	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
37	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
115	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
115	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
ALT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
ALT	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Alanine Aminotransferase	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Alanine Aminotransferase	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
23	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
23	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	

Units								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
U/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
U/L	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
10	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
10	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
67	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
67	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 1								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
AST	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
AST	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Aspartate Aminotransferase	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Aspartate Aminotransferase	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
20	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
20	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
U/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
U/L	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
14	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
14	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
48	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
48	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 1								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 3								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
BILI	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
BILI	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

Bilirubin	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Bilirubin	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.3	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.2	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.6	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.6	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CO2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CO2	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	

Test Name								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Carbon Dioxide	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Carbon Dioxide	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
26.6	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
26.6	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Units								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
mmol/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
mmol/L	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
24	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
24	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
33.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
33.2	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CREAT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CREAT	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Creatinine	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Creatinine	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.99	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.99	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Units							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.9	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Flag							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
H	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
H	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
N	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
N	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
GLUC	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
GLUC	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Glucose	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Glucose	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
100	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
100	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
73	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
73	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
105	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
105	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
K	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
K	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Potassium	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Potassium	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.5	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mEq/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mEq/L	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

3.7	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.7	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.2	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PROT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PROT	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Protein	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Protein	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.8	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
6.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
6.3	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
8.1	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
8.1	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
SODIUM	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
SODIUM	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Sodium	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Sodium	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
143	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
143	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Units							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mEq/L	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mEq/L	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
135	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
135	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
143	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
143	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 3								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
UEAN	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
UEAN	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Urea Nitrogen	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Urea Nitrogen	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

17	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Units							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
6	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
6	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							12
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
URATE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
URATE	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Uric Acid	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Uric Acid	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	

Test Result								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
5.1	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
5.1	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Units								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
mg/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
mg/dL	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
2.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
2.3	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
5.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
5.9	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:02 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b)(6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b)(6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b)(6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b)(6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b)(6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b)(6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b)(6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: End of Study
Visit Date: 15/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Hematology

Accession Number 18405905B
 Date of Collection 15/AUG/2018
 DD/MON/YYYY(EN)
 Time of Collection 19:58
 HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Basophils	0.0	Thou/uL	0	.1		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Basophils/Leukocytes	.5	%	0	2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Eosinophils	.2	Thou/uL	0	.5		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Eosinophils/Leukocytes	2.2	%	.5	7.4		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Hematocrit	48.1	%	35.3	47	H	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Hemoglobin	15.4	g/dL	12	15.9		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Lymphocytes	2.5	Thou/uL	1.1	3.2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Lymphocytes/Leukocytes	29.3	%	15.8	45.8		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Monocytes	.6	Thou/uL	.3	.9		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Monocytes/Leukocytes	6.8	%	4.9	12.8		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Neutrophils	5.2	Thou/uL	1.6	7.7		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Neutrophils/Leukocytes	61.0	%	38.4	74.2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Platelets	293	Thou/uL	155	361		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Erythrocytes	4.83	Mil/uL	3.95	5.21		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Leukocytes	8.5	Thou/uL	3.7	11.5		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:27 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:17:22 PM CT	(b)(6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:37:06 PM CT	(b)(6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b)(6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
HEME	False	- Empty -	1/16/2019 1:46:30 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HEME	True	- Empty -	1/28/2019 4:37:06 PM CT	(b)(6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
18405905B	False	- Empty -	1/16/2019 1:46:30 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18405905B	True	- Empty -	1/28/2019 4:37:06 PM CT	(b)(6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
15/AUG/2018	False	- Empty -	1/16/2019 1:46:30 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15/AUG/2018	True	- Empty -	1/28/2019 4:37:06 PM CT	(b)(6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	
19:58	False	- Empty -	1/16/2019 1:46:30 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

19:58	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
BASO	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
BASO	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Basophils	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Basophils	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
0.0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0.0	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

0	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.1	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.1	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
BASOLE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
BASOLE	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Basophils/Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Basophils/Leukocytes	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
2	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
EOS	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
EOS	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Eosinophils	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Eosinophils	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.2	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
EOSLE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
EOSLE	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Eosinophils/Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Eosinophils/Leukocytes	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
2.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
2.2	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.4	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.4	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HCT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HCT	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hematocrit	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hematocrit	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
48.1	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
48.1	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
35.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
35.3	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
47	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
47	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
H	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
H	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
N	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
N	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HGB	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HGB	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hemoglobin	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hemoglobin	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
15.4	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15.4	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
15.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15.9	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
LYM	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
LYM	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Lymphocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Lymphocytes	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
2.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
2.5	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
1.1	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
1.1	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
3.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
3.2	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 1								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew		

Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
LYMLE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
LYMLE	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Lymphocytes/Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Lymphocytes/Leukocytes	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
29.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
29.3	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
15.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15.8	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
45.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
45.8	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
MONO	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
MONO	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Monocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Monocytes	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.6	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.6	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

Thou/uL	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.3	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.3	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.9	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
MONOLE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
MONOLE	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Monocytes/Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Monocytes/Leukocytes	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
6.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
6.8	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

%	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.9	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.9	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12.8	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12.8	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEUT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEUT	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Neutrophils	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Neutrophils	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.2	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.6	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.6	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.7	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.7	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEUTLE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEUTLE	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Neutrophils/Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Neutrophils/Leukocytes	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
61.0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
61.0	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
38.4	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
38.4	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
74.2	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
74.2	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PLAT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PLAT	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Platelets	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Platelets	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
293	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
293	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
155	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
155	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
361	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
361	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							13
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
RBC	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
RBC	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Erythrocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Erythrocytes	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.83	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.83	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							14
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Mil/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Mil/uL	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.95	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.95	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.21	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.21	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							14

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
WBC	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
WBC	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Leukocytes	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Leukocytes	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
8.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
8.5	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Units							15

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.7	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.7	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
11.5	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
11.5	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:06 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name: End of Study
Visit Date: 15/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Urinalysis

Accession Number 18405906U
Date of Collection 15/AUG/2018
DD/MON/YYYY(EN)
Time of Collection 19:56
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Ketones	NEGATIVE		NEG, TRACE			Yes No Recheck				
Leukocyte Esterase	NEGATIVE		NEG, TRACE			Yes No Recheck				
Nitrite	NEGATIVE		NEGATIVE			Yes No Recheck				
Occult Blood	NEGATIVE		NEG, TRACE			Yes No Recheck				
pH	5.0		5.0	8.0		Yes No Recheck				
Specific Gravity	1.023		1.005	1.030		Yes No Recheck				
Urine Bilirubin	NEGATIVE		NEGATIVE			Yes No Recheck				
Urine Glucose	NEGATIVE		NEGATIVE			Yes No Recheck				
Urine Protein	NEGATIVE		NEG, TRACE			Yes No Recheck				
Urobilinogen	NEGATIVE		NEGATIVE			Yes No Recheck				

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:27 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UA	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UA	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18405906U	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18405906U	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
15/AUG/2018	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15/AUG/2018	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
19:56	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
19:56	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
KETONES	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
KETONES	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Ketones	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Ketones	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 4								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
LEUKASE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
LEUKASE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Leukocyte Esterase	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Leukocyte Esterase	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew		
Units								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
NEG, TRACE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	

NEG, TRACE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NITRITE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NITRITE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Nitrite	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Nitrite	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
OCCBLD	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
OCCBLD	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Occult Blood	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Occult Blood	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PH	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PH	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
pH	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
pH	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.0	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.0	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
8.0	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
8.0	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
SPGRAV	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
SPGRAV	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Specific Gravity	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Specific Gravity	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.023	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.023	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.005	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.005	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.030	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.030	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UBILI	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UBILI	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Bilirubin	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Bilirubin	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Units							7

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UGLUC	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UGLUC	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Glucose	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Glucose	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UPROT	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UPROT	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Protein	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Protein	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UROBIL	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UROBIL	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urobilinogen	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urobilinogen	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:30 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 1							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:17:37 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:37:09 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit	
Visit Not Done	<input checked="" type="checkbox"/>
Reason Not Done	SUBJECT WAS NOT CONTACTED IN ERROR
Visit Name	
Visit Date	B
Visit Number	
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/16/2018 11:40:11 AM CT	(b) (6)	CRA	001-Mathew
Incomplete	12/4/2018 7:27:01 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	12/4/2018 7:27:53 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	12/4/2018 8:45:38 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/13/2018 7:35:06 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Monitored	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Form: Visit							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Was a follow-up phone call made 7 days after their early term visit as required by the protocol?	10/16/2018 11:40:11 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	Will clarify query.	12/4/2018 7:27:53 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	Please document that the subject was not contacted via phone call as a protocol deviation.	12/4/2018 7:27:53 PM CT	(b) (6)	CRA	001-Mathew	

- Empty -	N/A	UPDATED AND DEVIATION WRITTEN	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Completed.	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBJECT WAS NOT CONTACTED IN ERROR	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBJECT WAS NOT CONTACTED IN ERROR	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) SUBJECT NOT CONTACTED	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Bypass appropriate and closed.	12/13/2018 7:35:06 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:30:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:12:19 AM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History					
Date	Change	Version	User	Role	
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole	
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration	
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration	
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration	
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration	
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration	
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration	

Trial Number: 22ndC_VLN **Visit Name:** iCRF **Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** **Subject Initials:**
Subject Number: 001018 **Current Time:**

Physical Examination - Symptom-driven

Did subject report any symptoms? ☒ No ☒ Yes

If No, reason not performed

Were there any abnormal findings? ☒ No ☒ Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/13/2018 7:35:06 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Monitored	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Did subject report any symptoms?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	(This item is required.) SUBJECT NOT CONTACTED	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Bypass appropriate and closed.	12/13/2018 7:35:06 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew	

If Yes, specify 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew	

Was the Physical Examination performed? 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew	

If No, reason not performed 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew	

Date of Examination 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew	

Were there any abnormal findings?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew	
Body System							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew	
Specify Abnormal Findings							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/13/2018 7:31:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:54 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Phone Call

Date of Call B ?

Was tobacco cessation information provided? B No Yes ?

Did Subject need to return to the clinic for a symptom driven physical exam? B No Yes ?

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/13/2018 7:31:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/13/2018 7:35:06 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Monitored	1/10/2019 3:01:58 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Date of Call							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) SUBJECT NOT CONTACTED	12/13/2018 7:31:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Bypass appropriate and closed.	12/13/2018 7:35:06 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:58 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) SUBJECT NOT CONTACTED	12/13/2018 7:31:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	Bypass appropriate and closed.	12/13/2018 7:35:06 AM CT	(b) (6)	Clinical Data Manager (CDM)	001- Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:58 PM CT	(b) (6)	CRA	001- Mathew	
Did Subject need to return to the clinic for a symptom driven physical exam?							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	(This item is required.) SUBJECT NOT CONTACTED	12/13/2018 7:31:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	Bypass appropriate and closed.	12/13/2018 7:35:06 AM CT	(b) (6)	Clinical Data Manager (CDM)	001- Mathew	
- Empty -	True	- Empty -	1/10/2019 3:01:58 PM CT	(b) (6)	CRA	001- Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** iCRF **Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** **Subject Initials:**
Subject Number: 001018 **Current Time:**

Adverse Events

Were any Adverse Events experienced? ☒ No ☒ Yes

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/13/2018 6:19:12 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Were any Adverse Events experienced?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	9/13/2018 6:19:12 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

AE-OCCIPITAL HEADACHE-01/AUG/2018

AE Number	1
Adverse Event	OCCIPITAL HEADACHE
Onset Date	01/AUG/2018 DD/MON/YYYY(EN)
Onset Time (24 Hour Clock)	17:30 HH:MM
Ongoing	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Resolved Date	02/AUG/2018 DD/MON/YYYY(EN)
Resolved Time (24 Hour Clock)	07:13 HH:MM
Frequency	Continuous
Severity	Mild
Serious Event?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Outcome	Resolved
Action taken with study product	Not Changed
Relationship to study product	Unlikely
What other action was taken in response to this adverse event?	ICE BAG GIVEN AT 20:00 ON 01AUG2018
Verbatim Term	OCCIPITAL HEADACHE
MedDRA LLT Name	Occipital headache
MedDRA LLT Code	10048968
MedDRA PT Name	Headache
MedDRA PT Code	10019211
MedDRA HLT Name	Headaches NEC
MedDRA HLT Code	10019233
MedDRA HLGT Name	Headaches
MedDRA HLGT Code	10019231
MedDRA SOC Name	Nervous system disorders
MedDRA SOC Code	10029205

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:11:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	10/7/2018 10:20:29 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 5:58:15 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17:30	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17:30	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/AUG/2018	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

02/AUG/2018	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:13	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:13	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NOT CHANGED	False	Transcription Error	10/9/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	11/27/2018 5:58:15 PM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNLIKELY	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNLIKELY	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ICE BAG GIVEN AT 20:00 ON 01AUG2018	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ICE BAG GIVEN AT 20:00 ON 01AUG2018	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE	False	Question value " updated to 'OCCIPITAL HEADACHE' by VTS based on DataChange editId 176.	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
OCCIPITAL HEADACHE	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Occipital headache	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Occipital headache	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
10048968	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10048968	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Name							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Headache	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Headache	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
10019211	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10019211	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Headaches NEC	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Headaches NEC	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
10019233	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10019233	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Headaches	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Headaches	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
10019231	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10019231	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Name							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Nervous system disorders	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Nervous system disorders	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
10029205	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10029205	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE_2018/08/01_MILD_CONTINUOUS_N_RESOLVED_UNLIKELY	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE_2018/08/01_MILD_CONTINUOUS_N_RESOLVED_UNLIKELY	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:09:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE_2018/08/01_MILD_CONTINUOUS_N_RESOLVED_UNLIKELY	False	- Empty -	8/24/2018 3:10:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE_2018/08/01_MILD_CONTINUOUS_N_RESOLVED_UNLIKELY	True	- Empty -	9/13/2018 6:19:58 PM CT	(b) (6)	CRA	001-Mathew	

ICRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN	Visit Name:	iCRF Status: Signed Locked
Subject Caption: 001018	Visit Date:	Subject Initials:
Subject Number: 001018	Current Time:	

AE-NIGHTMARES-04/AUG/2018	
AE Number	2
Adverse Event	NIGHTMARES
Onset Date	04/AUG/2018 DD/MON/YYYY(EN)
Onset Time (24 Hour Clock)	01:30 HH:MM
Ongoing	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Resolved Date	15/AUG/2018 DD/MON/YYYY(EN)
Resolved Time (24 Hour Clock)	07:45 HH:MM
Frequency	Intermittent
Severity	Mild
Serious Event?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Outcome	Resolved
Action taken with study product	Not Changed
Relationship to study product	Possible
What other action was taken in response to this adverse event?	NONE
Verbatim Term	NIGHTMARES
MedDRA LLT Name	Nightmares
MedDRA LLT Code	10029414
MedDRA PT Name	Nightmare
MedDRA PT Code	10029412
MedDRA HLT Name	Parasomnias
MedDRA HLT Code	10033920
MedDRA HLGT Name	Sleep disorders and disturbances
MedDRA HLGT Code	10040991
MedDRA SOC Name	Psychiatric disorders
MedDRA SOC Code	10037175

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/28/2018 5:28:26 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	10/7/2018 10:20:39 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:01:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 5:58:31 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NIGHTMARES	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NIGHTMARES	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
04/AUG/2018	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
04/AUG/2018	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01:30	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01:30	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:45	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:45	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTERMITTENT	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTERMITTENT	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	8/24/2018 3:12:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	False	- Empty -	8/24/2018 3:12:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b)(6)	TBMigration	001-Mathew	
NOT CHANGED	False	Transcription Error	10/9/2018 1:01:32 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	11/27/2018 5:58:31 PM CT	(b)(6)	CRA	001-Mathew	

Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	False	- Empty -	8/24/2018 3:12:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	

What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	False	- Empty -	8/24/2018 3:12:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	

Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
NIGHTMARES	False	Question value " updated to 'NIGHTMARES' by VTS based on DataChange editId 176.	8/28/2018 5:28:26 PM CT	(b)(6)	Setup Administrator	001-Mathew	
NIGHTMARES	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	

MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:26 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
Nightmares	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Nightmares	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:26 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
10029414	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10029414	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:26 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	
Nightmare	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Nightmare	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:26 PM CT	(b)(6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b)(6)	CRA	001-Mathew	

10029412	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10029412	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:26 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Parasomnias	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Parasomnias	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:26 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
10033920	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10033920	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGHT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:26 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Sleep disorders and disturbances	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Sleep disorders and disturbances	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGHT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:26 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
10040991	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10040991	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:26 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
Psychiatric disorders	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Psychiatric disorders	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:26 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew	
10037175	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10037175	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

Not a true data. Flag is used for New SAE Notification.								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew		
Not a true data. Concatenated field used for Updated SAE Notification.								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NIGHTMARES_2018/08/04_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NIGHTMARES_2018/08/04_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew		
Not a true data. Flag is used for SAE comparison.								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:11:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NIGHTMARES_2018/08/04_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:12:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NIGHTMARES_2018/08/04_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:20:27 PM CT	(b) (6)	CRA	001-Mathew		

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN	Visit Name:	iCRF Status: Signed Locked
Subject Caption: 001018	Visit Date:	Subject Initials:
Subject Number: 001018	Current Time:	

AE-HEAVINESS TO CHEST-08/AUG/2018

AE Number	3
Adverse Event	HEAVINESS TO CHEST
Onset Date	08/AUG/2018 DD/MON/YYYY(EN)
Onset Time (24 Hour Clock)	18:30 HH:MM
Ongoing	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Resolved Date	08/AUG/2018 DD/MON/YYYY(EN)
Resolved Time (24 Hour Clock)	19:00 HH:MM
Frequency	Continuous
Severity	Mild
Serious Event?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes

Outcome	Resolved
Action taken with study product	Not Changed
Relationship to study product	Possible
What other action was taken in response to this adverse event?	NONE

Verbatim Term	HEAVINESS TO CHEST
MedDRA LLT Name	Chest heaviness
MedDRA LLT Code	10008475
MedDRA PT Name	Chest discomfort
MedDRA PT Code	10008469
MedDRA HLT Name	Pain and discomfort NEC
MedDRA HLT Code	10033372
MedDRA HLGT Name	General system disorders NEC
MedDRA HLGT Code	10018073
MedDRA SOC Name	General disorders and administration site conditions
MedDRA SOC Code	10018065

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	10/7/2018 10:20:49 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:01:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 5:58:47 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08/AUG/2018	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08/AUG/2018	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18:30	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18:30	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

08/AUG/2018	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08/AUG/2018	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:00	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:00	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	

Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NOT CHANGED	False	Transcription Error	10/9/2018 1:01:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	11/27/2018 5:58:47 PM CT	(b) (6)	CRA	001-Mathew	

Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	

What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	

Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST	False	Question value " updated to 'HEAVINESS TO CHEST' by VTS based on DataChange editId 176.	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
HEAVINESS TO CHEST	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	

MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Chest heaviness	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Chest heaviness	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
10008475	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10008475	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Chest discomfort	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Chest discomfort	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
10008469	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10008469	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Pain and discomfort NEC	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
Pain and discomfort NEC	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
10033372	True	- Empty -	9/24/2018 11:53:00 AM CT	tmsystem	TBRole	001-Mathew	
10033372	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
General system disorders NEC	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	

General system disorders NEC	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001- Mathew	
MedDRA HLG Code							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
10018073	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10018073	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Name							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
General disorders and administration site conditions	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
General disorders and administration site conditions	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Code							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
10018065	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10018065	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:12:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:13:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:20:50 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN	Visit Name:	iCRF Status: Signed Locked
Subject Caption: 001018	Visit Date:	Subject Initials:
Subject Number: 001018	Current Time:	

AE-ANXIETY-08/AUG/2018	
AE Number	4
Adverse Event	ANXIETY
Onset Date	08/AUG/2018 DD/MON/YYYY(EN)
Onset Time (24 Hour Clock)	18:30 HH:MM
Ongoing	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Resolved Date	08/AUG/2018 DD/MON/YYYY(EN)
Resolved Time (24 Hour Clock)	19:00 HH:MM
Frequency	Continuous
Severity	Mild
Serious Event?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Outcome	Resolved
Action taken with study product	Not Changed
Relationship to study product	Possible
What other action was taken in response to this adverse event?	NONE
Verbatim Term	ANXIETY
MedDRA LLT Name	Anxiety
MedDRA LLT Code	10002855
MedDRA PT Name	Anxiety
MedDRA PT Code	10002855
MedDRA HLT Name	Anxiety symptoms
MedDRA HLT Code	10002869
MedDRA HLGT Name	Anxiety disorders and symptoms
MedDRA HLGT Code	10002861
MedDRA SOC Name	Psychiatric disorders
MedDRA SOC Code	10037175

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew
Complete	9/26/2018 2:32:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/26/2018 2:32:58 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	9/28/2018 2:46:00 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	10/7/2018 10:20:59 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:01:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 5:59:04 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
ANXIETY	False	Transcription Error	9/26/2018 2:32:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ANXIETY	True	- Empty -	9/28/2018 2:46:00 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08/AUG/2018	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08/AUG/2018	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18:30	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18:30	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08/AUG/2018	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08/AUG/2018	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:00	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:00	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

tored?							
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NOT CHANGED	False	Transcription Error	10/9/2018 1:01:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	11/27/2018 5:59:04 PM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION	False	Question value " updated to 'SUICIDAL IDEATION' by VTS based on DataChange editId 176.	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew	
SUICIDAL IDEATION	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
ANXIETY	False	Question value 'SUICIDAL IDEATION' updated to 'ANXIETY' by VTS based on DataChange editId 176.	9/26/2018 2:32:58 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ANXIETY	True	- Empty -	9/28/2018 2:46:00 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Suicidal ideation	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:33:00 PM CT	tmsystem	TBRole	001-Mathew	
Anxiety	True	- Empty -	9/28/2018 10:57:00 AM CT	tmsystem	TBRole	001-Mathew	
Anxiety	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
10042458	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:33:00 PM CT	tmsystem	TBRole	001-Mathew	
10002855	True	- Empty -	9/28/2018 10:57:00 AM CT	tmsystem	TBRole	001-Mathew	
10002855	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Suicidal ideation	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:33:00 PM CT	tmsystem	TBRole	001-Mathew	
Anxiety	True	- Empty -	9/28/2018 10:57:00 AM CT	tmsystem	TBRole	001-Mathew	
Anxiety	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
10042458	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:33:00 PM CT	tmsystem	TBRole	001-Mathew	
10002855	True	- Empty -	9/28/2018 10:57:00 AM CT	tmsystem	TBRole	001-Mathew	
10002855	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Suicidal and self-injurious behaviour	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:33:00 PM CT	tmsystem	TBRole	001-Mathew	
Anxiety symptoms	True	- Empty -	9/28/2018 10:57:00 AM CT	tmsystem	TBRole	001-Mathew	
Anxiety symptoms	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

MedDRA HLT Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew		
10042459	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
- Empty -	True	- Empty -	9/26/2018 2:33:00 PM CT	tmsystem	TBRole	001-Mathew		
10002869	True	- Empty -	9/28/2018 10:57:00 AM CT	tmsystem	TBRole	001-Mathew		
10002869	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA HLGT Name								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew		
Suicidal and self-injurious behaviours NEC	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
- Empty -	True	- Empty -	9/26/2018 2:33:00 PM CT	tmsystem	TBRole	001-Mathew		
Anxiety disorders and symptoms	True	- Empty -	9/28/2018 10:57:00 AM CT	tmsystem	TBRole	001-Mathew		
Anxiety disorders and symptoms	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA HLGT Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew		
10042460	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
- Empty -	True	- Empty -	9/26/2018 2:33:00 PM CT	tmsystem	TBRole	001-Mathew		
10002861	True	- Empty -	9/28/2018 10:57:00 AM CT	tmsystem	TBRole	001-Mathew		
10002861	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA SOC Name								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew		
Psychiatric disorders	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
- Empty -	True	- Empty -	9/26/2018 2:33:00 PM CT	tmsystem	TBRole	001-Mathew		
Psychiatric disorders	True	- Empty -	9/28/2018 10:57:00 AM CT	tmsystem	TBRole	001-Mathew		
Psychiatric disorders	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA SOC Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		

- Empty -	False	- Empty -	8/28/2018 5:28:36 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
10037175	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:33:00 PM CT	tmsystem	TBRole	001-Mathew	
10037175	True	- Empty -	9/28/2018 10:57:00 AM CT	tmsystem	TBRole	001-Mathew	
10037175	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
ANXIETY_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	9/26/2018 2:32:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ANXIETY_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/28/2018 2:46:00 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:13:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:14:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:21:29 PM CT	(b) (6)	CRA	001-Mathew	
ANXIETY_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	9/26/2018 2:32:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ANXIETY_2018/08/08_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/28/2018 2:46:00 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN	Visit Name:	iCRF Status: Signed Locked
Subject Caption: 001018	Visit Date:	Subject Initials:
Subject Number: 001018	Current Time:	

AE-HEAVINESS TO CHEST-14/AUG/2018

AE Number	5	
Adverse Event	HEAVINESS TO CHEST	
Onset Date	14/AUG/2018	
	DD/MON/YYYY(EN)	
Onset Time (24 Hour Clock)	19:30	
	HH:MM	
Ongoing	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
Resolved Date	14/AUG/2018	
	DD/MON/YYYY(EN)	
Resolved Time (24 Hour Clock)	22:30	
	HH:MM	
Frequency	Intermittent	
Severity	Mild	
Serious Event?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	

Outcome	Resolved
Action taken with study product	Not Changed
Relationship to study product	Possible
What other action was taken in response to this adverse event?	NONE

Verbatim Term	HEAVINESS TO CHEST
MedDRA LLT Name	Chest heaviness
MedDRA LLT Code	10008475
MedDRA PT Name	Chest discomfort
MedDRA PT Code	10008469
MedDRA HLT Name	Pain and discomfort NEC
MedDRA HLT Code	10033372
MedDRA HLGt Name	General system disorders NEC
MedDRA HLGt Code	10018073
MedDRA SOC Name	General disorders and administration site conditions
MedDRA SOC Code	10018065

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew
Complete	9/27/2018 8:14:37 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/28/2018 2:46:10 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	10/7/2018 10:21:09 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:02:10 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	11/27/2018 6:10:40 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/4/2018 11:15:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:14:21 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:30	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:30	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:00	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:00	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
20:00	False	Per the AE report this is listed as 22:30:00. Please verify.	11/27/2018 6:10:40 PM CT	(b) (6)	CRA	001-Mathew	
22:30	False	Transcription Error	12/4/2018 11:15:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
22:30	False	updated	12/4/2018 11:15:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
22:30	True	Updated.	12/4/2018 7:14:21 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
INTERMITTENT	False	Recording Error	9/27/2018 8:14:37 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTERMITTENT	True	- Empty -	9/28/2018 2:46:10 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	

Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NOT CHANGED	False	Transcription Error	10/9/2018 1:02:10 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	11/27/2018 6:10:40 PM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST	False	Question value " updated to 'HEAVINESS TO CHEST' by VTS based on DataChange editId 176.	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
HEAVINESS TO CHEST	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Name							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Chest heaviness	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Chest heaviness	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
10008475	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10008475	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Chest discomfort	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Chest discomfort	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
10008469	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10008469	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Pain and discomfort NEC	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Pain and discomfort NEC	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	

10033372	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10033372	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
General system disorders NEC	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
General system disorders NEC	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
10018073	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10018073	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
General disorders and administration site conditions	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
General disorders and administration site conditions	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:41 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
10018065	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10018065	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
HEAVINESS TO CHEST_2018/08/14_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	False	- Empty -	9/27/2018 8:14:37 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST_2018/08/14_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	True	- Empty -	9/28/2018 2:46:10 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:14:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:21:43 PM CT	(b) (6)	CRA	001-Mathew	
HEAVINESS TO CHEST_2018/08/14_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	False	- Empty -	9/27/2018 8:14:37 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEAVINESS TO CHEST_2018/08/14_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	True	- Empty -	9/28/2018 2:46:10 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN	Visit Name:	iCRF Status: Signed Locked
Subject Caption: 001018	Visit Date:	Subject Initials:
Subject Number: 001018	Current Time:	

AE-FEELING SAD-14/AUG/2018		+
AE Number	6	+
Adverse Event	FEELING SAD	+
Onset Date	14/AUG/2018 DD/MON/YYYY(EN)	+
Onset Time (24 Hour Clock)	19:30 HH:MM	+
Ongoing	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	+
Resolved Date	14/AUG/2018 DD/MON/YYYY(EN)	+
Resolved Time (24 Hour Clock)	20:00 HH:MM	+
Frequency	Continuous	+
Severity	Mild	+
Serious Event?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	+
Outcome	Resolved	+
Action taken with study product	Not Changed	≡
Relationship to study product	Possible	+
What other action was taken in response to this adverse event?	NONE	+
Verbatim Term	FEELING SAD	≡
MedDRA LLT Name	Feeling sad	+
MedDRA LLT Code	10016364	+
MedDRA PT Name	Depressed mood	+
MedDRA PT Code	10012374	+
MedDRA HLT Name	Mood alterations with depressive symptoms	+
MedDRA HLT Code	10027938	+
MedDRA HLGT Name	Depressed mood disorders and disturbances	+
MedDRA HLGT Code	10012375	+
MedDRA SOC Name	Psychiatric disorders	+
MedDRA SOC Code	10037175	+

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	10/7/2018 10:21:19 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:02:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 6:10:56 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
6	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
6	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
FEELING SAD	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
FEELING SAD	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:30	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:30	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:00	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:00	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	

Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NOT CHANGED	False	Transcription Error	10/9/2018 1:02:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	11/27/2018 6:10:56 PM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
FEELING SAD	False	Question value " updated to 'FEELING SAD' by VTS based on DataChange editId 176.	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
FEELING SAD	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Feeling sad	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Feeling sad	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA LLT Code							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
10016364	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10016364	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Depressed mood	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Depressed mood	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
10012374	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10012374	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Mood alterations with depressive symptoms	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Mood alterations with depressive symptoms	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
10027938	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10027938	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Depressed mood disorders and disturbances	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Depressed mood disorders and disturbances	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLG Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
10012375	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10012375	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Psychiatric disorders	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Psychiatric disorders	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:46 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
10037175	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10037175	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
FEELING SAD_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
FEELING SAD_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:15:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
FEELING SAD_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:16:14 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
FEELING SAD_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:21:55 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN	Visit Name:	iCRF Status: Signed Locked
Subject Caption: 001018	Visit Date:	Subject Initials:
Subject Number: 001018	Current Time:	

AE-GENERALIZED BODY SHAKES-14/AUG/2018		+
AE Number	7	+
Adverse Event	GENERALIZED BODY SHAKES	+
Onset Date	14/AUG/2018 DD/MON/YYYY(EN)	+
Onset Time (24 Hour Clock)	19:30 HH:MM	+
Ongoing	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	+
Resolved Date	14/AUG/2018 DD/MON/YYYY(EN)	+
Resolved Time (24 Hour Clock)	20:00 HH:MM	+
Frequency	Intermittent	+
Severity	Mild	+
Serious Event?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	+
Outcome		Resolved
Action taken with study product		Not Changed
Relationship to study product		Possible
What other action was taken in response to this adverse event?		NONE
Verbatim Term		GENERALIZED BODY SHAKES
MedDRA LLT Name	Shaking	+
MedDRA LLT Code	10040528	+
MedDRA PT Name	Tremor	+
MedDRA PT Code	10044565	+
MedDRA HLT Name	Tremor (excl congenital)	+
MedDRA HLT Code	10044566	+
MedDRA HLGT Name	Movement disorders (incl parkinsonism)	+
MedDRA HLGT Code	10028037	+
MedDRA SOC Name	Nervous system disorders	+
MedDRA SOC Code	10029205	+

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	10/7/2018 10:21:29 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:02:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 6:11:11 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
7	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
7	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GENERALIZED BODY SHAKES	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GENERALIZED BODY SHAKES	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:30	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:30	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:00	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:00	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTERMITTENT	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTERMITTENT	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	

Action taken with study product								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
DOSE NOT CHANGED	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
DOSE NOT CHANGED	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew		
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew		
NOT CHANGED	False	Transcription Error	10/9/2018 1:02:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NOT CHANGED	True	- Empty -	11/27/2018 6:11:11 PM CT	(b) (6)	CRA	001-Mathew		
Relationship to study product								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
POSSIBLE	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
POSSIBLE	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew		
What other action was taken in response to this adverse event?								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NONE	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NONE	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew		
Verbatim Term								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
GENERALIZED BODY SHAKES	False	Question value " updated to 'GENERALIZED BODY SHAKES' by VTS based on DataChange editId 176.	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew		
GENERALIZED BODY SHAKES	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew		
MedDRA LLT Name								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew		
Shaking	True	- Empty -	10/19/2018 1:44:00 PM CT	tmsystem	TBRole	001-Mathew		
Shaking	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA LLT Code								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew		

10040528	True	- Empty -	10/19/2018 1:44:00 PM CT	tmsystem	TBRole	001-Mathew	
10040528	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Tremor	True	- Empty -	10/19/2018 1:44:00 PM CT	tmsystem	TBRole	001-Mathew	
Tremor	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
10044565	True	- Empty -	10/19/2018 1:44:00 PM CT	tmsystem	TBRole	001-Mathew	
10044565	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Tremor (excl congenital)	True	- Empty -	10/19/2018 1:44:00 PM CT	tmsystem	TBRole	001-Mathew	
Tremor (excl congenital)	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
10044566	True	- Empty -	10/19/2018 1:44:00 PM CT	tmsystem	TBRole	001-Mathew	
10044566	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Movement disorders (incl parkinsonism)	True	- Empty -	10/19/2018 1:44:00 PM CT	tmsystem	TBRole	001-Mathew	
Movement disorders (incl parkinsonism)	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
10028037	True	- Empty -	10/19/2018 1:44:00 PM CT	tmsystem	TBRole	001-Mathew	
10028037	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Nervous system disorders	True	- Empty -	10/19/2018 1:44:00 PM CT	tmsystem	TBRole	001-Mathew	
Nervous system disorders	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:51 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
10029205	True	- Empty -	10/19/2018 1:44:00 PM CT	tmsystem	TBRole	001-Mathew	
10029205	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GENERALIZED BODY SHAKES_2018/08/14_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GENERALIZED BODY SHAKES_2018/08/14_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:16:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

GENERALIZED BODY SHAKES_2018/08/14_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:17:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
GENERALIZED BODY SHAKES_2018/08/14_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:22:11 PM CT	(b) (6)	CRA	001- Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

AE-ANXIETY-14/AUG/2018	
AE Number	8
Adverse Event	ANXIETY
Onset Date	14/AUG/2018 DD/MON/YYYY(EN)
Onset Time (24 Hour Clock)	19:30 HH:MM
Ongoing	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Resolved Date	14/AUG/2018 DD/MON/YYYY(EN)
Resolved Time (24 Hour Clock)	20:00 HH:MM
Frequency	Continuous
Severity	Mild
Serious Event?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Outcome	Resolved
Action taken with study product	Study Product Withdrawn
Relationship to study product	Possible
What other action was taken in response to this adverse event?	NONE
Verbatim Term	ANXIETY
MedDRA LLT Name	Anxiety
MedDRA LLT Code	10002855
MedDRA PT Name	Anxiety
MedDRA PT Code	10002855
MedDRA HLT Name	Anxiety symptoms
MedDRA HLT Code	10002869
MedDRA HLGT Name	Anxiety disorders and symptoms
MedDRA HLGT Code	10002861
MedDRA SOC Name	Psychiatric disorders
MedDRA SOC Code	10037175

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew

Complete	9/26/2018 2:33:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/26/2018 2:33:13 PM CT	(b)(6)	Setup Administrator	001-Mathew
Monitored	9/28/2018 2:46:18 PM CT	(b)(6)	CRA	001-Mathew
Incomplete	10/7/2018 10:21:39 PM CT	(b)(6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:02:48 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 6:11:27 PM CT	(b)(6)	CRA	001-Mathew
Partial Monitored	12/4/2018 7:30:20 PM CT	(b)(6)	CRA	001-Mathew
Complete	12/5/2018 7:18:17 AM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	12/5/2018 10:54:46 AM CT	(b)(6)	CRA	001-Mathew
Complete	12/13/2018 8:50:36 AM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:04:55 PM CT	(b)(6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b)(6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
8	False	- Empty -	8/24/2018 3:18:07 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
8	True	- Empty -	9/13/2018 6:22:27 PM CT	(b)(6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION	False	- Empty -	8/24/2018 3:18:07 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION	True	- Empty -	9/13/2018 6:22:27 PM CT	(b)(6)	CRA	001-Mathew	
ANXIETY	False	Transcription Error	9/26/2018 2:33:13 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
ANXIETY	True	- Empty -	9/28/2018 2:46:18 PM CT	(b)(6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	False	- Empty -	8/24/2018 3:18:07 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	True	- Empty -	9/13/2018 6:22:27 PM CT	(b)(6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:30	False	- Empty -	8/24/2018 3:18:07 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:30	True	- Empty -	9/13/2018 6:22:27 PM CT	(b)(6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:00	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20:00	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	

Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NOT CHANGED	False	Transcription Error	10/9/2018 1:02:48 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	11/27/2018 6:11:27 PM CT	(b) (6)	CRA	001-Mathew	
NOT CHANGED	False	As the reason for ET was listed as due to this AE, should this be changed to subject withdrawn?	12/4/2018 7:30:20 PM CT	(b) (6)	CRA	001-Mathew	
DRUG WITHDRAWN	False	Transcription Error	12/5/2018 7:18:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DRUG WITHDRAWN	False	updated in edc and source is being updated	12/5/2018 7:18:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DRUG WITHDRAWN	False	AE report updated	12/13/2018 8:50:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DRUG WITHDRAWN	True	Corrected.	1/10/2019 3:04:55 PM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION	False	Question value " updated to 'SUICIDAL IDEATION' by VTS based on DataChange editId 176.	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
SUICIDAL IDEATION	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	

ANXIETY	False	Question value 'SUICIDAL IDEATION' updated to 'ANXIETY' by VTS based on DataChange editld 176.	9/26/2018 2:33:13 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ANXIETY	True	- Empty -	9/28/2018 2:46:18 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Suicidal ideation	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:34:00 PM CT	tmsystem	TBRole	001-Mathew	
Anxiety	True	- Empty -	12/19/2018 5:08:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
10042458	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:34:00 PM CT	tmsystem	TBRole	001-Mathew	
10002855	True	- Empty -	12/19/2018 5:08:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Suicidal ideation	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:34:00 PM CT	tmsystem	TBRole	001-Mathew	
Anxiety	True	- Empty -	12/19/2018 5:08:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
10042458	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:34:00 PM CT	tmsystem	TBRole	001-Mathew	
10002855	True	- Empty -	12/19/2018 5:08:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -		False	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -		False	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -		True	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	

Suicidal and self-injurious behaviour	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:34:00 PM CT	tmsystem	TBRole	001-Mathew	
Anxiety symptoms	True	- Empty -	12/19/2018 5:08:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
10042459	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:34:00 PM CT	tmsystem	TBRole	001-Mathew	
10002869	True	- Empty -	12/19/2018 5:08:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Suicidal and self-injurious behaviours NEC	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:34:00 PM CT	tmsystem	TBRole	001-Mathew	
Anxiety disorders and symptoms	True	- Empty -	12/19/2018 5:08:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
10042460	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:34:00 PM CT	tmsystem	TBRole	001-Mathew	
10002861	True	- Empty -	12/19/2018 5:08:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Psychiatric disorders	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:34:00 PM CT	tmsystem	TBRole	001-Mathew	
Psychiatric disorders	True	- Empty -	12/19/2018 5:08:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/28/2018 5:28:56 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
10037175	True	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
- Empty -	True	- Empty -	9/26/2018 2:34:00 PM CT	tmsystem	TBRole	001-Mathew	
10037175	True	- Empty -	12/19/2018 5:08:01 AM CT	tmsystem	TBRole	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
ANXIETY_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	9/26/2018 2:33:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ANXIETY_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/28/2018 2:46:18 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:17:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	8/24/2018 3:18:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUICIDAL IDEATION_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/13/2018 6:22:27 PM CT	(b) (6)	CRA	001-Mathew	
ANXIETY_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	9/26/2018 2:33:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ANXIETY_2018/08/14_MILD_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	9/28/2018 2:46:18 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

AE-GENERALIZED HEADACHE-14/AUG/2018

AE Number	10
Adverse Event	GENERALIZED HEADACHE
Onset Date	14/AUG/2018 DD/MON/YYYY(EN)
Onset Time (24 Hour Clock)	21:30 HH:MM
Ongoing	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Resolved Date	
Resolved Time (24 Hour Clock)	
Frequency	Continuous
Severity	Mild
Serious Event?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Outcome	Unknown (lost to follow-up)
Action taken with study product	Not Changed
Relationship to study product	Possible
What other action was taken in response to this adverse event?	UNKNOWN
Verbatim Term	GENERALIZED HEADACHE
MedDRA LLT Name	Headache
MedDRA LLT Code	10019211
MedDRA PT Name	Headache
MedDRA PT Code	10019211
MedDRA HLT Name	Headaches NEC
MedDRA HLT Code	10019233
MedDRA HLGT Name	Headaches
MedDRA HLGT Code	10019231
MedDRA SOC Name	Nervous system disorders
MedDRA SOC Code	10029205

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	8/28/2018 5:29:06 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	10/7/2018 10:21:49 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:03:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 6:13:17 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	

Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GENERALIZED HEADACHE	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GENERALIZED HEADACHE	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	

Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/AUG/2018	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	

Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
21:30	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
21:30	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	

Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

Y	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	

Was an autopsy performed?								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew		
Outcome								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
UNKNOWN (LOST TO FOLLOW-UP)	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
UNKNOWN (LOST TO FOLLOW-UP)	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew		
Action taken with study product								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
DOSE NOT CHANGED	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
DOSE NOT CHANGED	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew		
- Empty -	True	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew		
NOT CHANGED	False	Transcription Error	10/9/2018 1:03:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NOT CHANGED	True	- Empty -	11/27/2018 6:13:17 PM CT	(b) (6)	CRA	001-Mathew		
Relationship to study product								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
POSSIBLE	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
POSSIBLE	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew		
What other action was taken in response to this adverse event?								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
UNKNOWN	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
UNKNOWN	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew		
Verbatim Term								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		

GENERALIZED HEADACHE	False	Question value " updated to 'GENERALIZED HEADACHE' by VTS based on DataChange editId 176.	8/28/2018 5:29:06 PM CT	(b) (6)	Setup Administrator	001-Mathew	
GENERALIZED HEADACHE	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Headache	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Headache	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Headache	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10019211	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10019211	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
10019211	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Headache	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Headache	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Headache	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10019211	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10019211	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
10019211	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Headaches NEC	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Headaches NEC	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Headaches NEC	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10019233	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	

10019233	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
10019233	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Headaches	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Headaches	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Headaches	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10019231	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10019231	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
10019231	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Nervous system disorders	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Nervous system disorders	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Nervous system disorders	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10029205	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10029205	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
10029205	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

GENERALIZED HEADACHE_2018/08/14_MILD_CONTINUOUS_N_ _POSSIBLE	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
GENERALIZED HEADACHE_2018/08/14_MILD_CONTINUOUS_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
GENERALIZED HEADACHE_2018/08/14_MILD_CONTINUOUS_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001- Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:19:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
GENERALIZED HEADACHE_2018/08/14_MILD_CONTINUOUS_N_ _POSSIBLE	False	- Empty -	8/24/2018 3:20:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
GENERALIZED HEADACHE_2018/08/14_MILD_CONTINUOUS_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	False	- Empty -	9/14/2018 9:09:23 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
GENERALIZED HEADACHE_2018/08/14_MILD_CONTINUOUS_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	True	- Empty -	9/28/2018 2:47:02 PM CT	(b) (6)	CRA	001- Mathew	

iCRF Version Change History					
Date	Change	Version	User	Role	
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole	
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration	
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration	
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration	
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration	
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration	
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration	

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

AE-NAUSEA

AE Number	11
Adverse Event	NAUSEA
Onset Date	<input type="text"/> <input type="text"/>
Onset Time (24 Hour Clock)	<input type="text"/> UNK:UNK HH:MM
Ongoing	<input type="text"/> No <input type="text"/> Yes
Resolved Date	<input type="text"/>
Resolved Time (24 Hour Clock)	<input type="text"/>
Frequency	Single Episode
Severity	Mild
Serious Event?	<input type="text"/> No <input type="text"/> Yes
Outcome	Unknown (lost to follow-up)
Action taken with study product	Not Changed
Relationship to study product	Possible
What other action was taken in response to this adverse event?	CON MED GIVEN
Verbatim Term	NAUSEA
MedDRA LLT Name	Nausea
MedDRA LLT Code	10028813
MedDRA PT Name	Nausea
MedDRA PT Code	10028813
MedDRA HLT Name	Nausea and vomiting symptoms
MedDRA HLT Code	10028817
MedDRA HLGT Name	Gastrointestinal signs and symptoms
MedDRA HLGT Code	10018012
MedDRA SOC Name	Gastrointestinal disorders
MedDRA SOC Code	10017947

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	1/16/2019 9:37:24 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	2/7/2019 10:57:25 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/11/2019 9:38:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew
Monitored	2/13/2019 12:04:28 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	3/1/2019 1:26:37 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Partial Monitored	3/1/2019 1:31:01 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Complete	3/5/2019 1:27:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	3/5/2019 5:04:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Monitored	3/6/2019 10:10:10 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
11	False	- Empty -	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
11	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA	False	- Empty -	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) START DATE IS UNKNOWN	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	Correct per source.	2/7/2019 10:57:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	Please update to UNK, provide what fields you can (like month/year).	3/1/2019 1:26:37 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	START DATE IS UNKNOWN, THERE IS A NOTE FOR THIS	3/5/2019 1:27:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Data updated/provided, query closed.	3/5/2019 5:04:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	True	- Empty -	3/6/2019 10:10:10 AM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) START TIME IS UNKNOWN	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Correct per source.	2/7/2019 10:57:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	Please update to unknown.	3/1/2019 1:31:01 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
UNK:UNK	False	Transcription Error	3/5/2019 1:27:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	UPDATED	3/5/2019 1:27:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	Data updated/provided, query closed.	3/5/2019 5:04:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
UNK:UNK	True	- Empty -	3/6/2019 10:10:10 AM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) UNKNOWN	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Correct per source.	2/7/2019 10:57:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	STOP DATE IS UNKNOWN	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	STOP TIME IS UNKNOWN	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SINGLE EPISODE	False	- Empty -	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SINGLE EPISODE	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNKNOWN (LOST TO FOLLOW-UP)	False	- Empty -	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNKNOWN (LOST TO FOLLOW-UP)	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	False	- Empty -	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Please request the PI to add the relationship code to the source and update the CRF.	2/7/2019 10:57:25 PM CT	(b) (6)	CRA	001-Mathew	
POSSIBLE	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	False	updated	2/11/2019 9:38:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	Updated.	2/13/2019 12:04:28 PM CT	(b) (6)	CRA	001-Mathew	
What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CON MED GIVEN	False	- Empty -	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CON MED GIVEN	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA	False	Question value " updated to 'NAUSEA' by VTS based on DataChange editId 3243.	1/16/2019 9:37:24 AM CT	(b) (6)	Setup Administrator	001-Mathew	
NAUSEA	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	

MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Nausea	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Nausea	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	

MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10028813	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10028813	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	

MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Nausea	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Nausea	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	

MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10028813	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10028813	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	

MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Nausea and vomiting symptoms	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Nausea and vomiting symptoms	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10028817	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10028817	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Gastrointestinal signs and symptoms	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Gastrointestinal signs and symptoms	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10018012	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10018012	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Gastrointestinal disorders	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Gastrointestinal disorders	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10017947	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10017947	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_	False	- Empty -	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:33:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_	False	- Empty -	1/16/2019 9:37:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	False	- Empty -	2/11/2019 9:37:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	True	- Empty -	2/12/2019 4:14:45 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

AE-CONSTIPATION	
AE Number	12
Adverse Event	CONSTIPATION
Onset Date	B ?
Onset Time (24 Hour Clock)	B UNK:UNK HH:MM ?
Ongoing	B <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes ?
Resolved Date	⋮
Resolved Time (24 Hour Clock)	⋮
Frequency	Single Episode +
Severity	Mild +
Serious Event?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes +
Outcome	Unknown (lost to follow-up) +
Action taken with study product	Not Changed +
Relationship to study product	Possible ?
What other action was taken in response to this adverse event?	CON MED GIVEN +
Verbatim Term	CONSTIPATION ⋮
MedDRA LLT Name	Constipation +
MedDRA LLT Code	10010774 +
MedDRA PT Name	Constipation +
MedDRA PT Code	10010774 +
MedDRA HLT Name	Gastrointestinal atonic and hypomotility disorders NEC +
MedDRA HLT Code	10017933 +
MedDRA HLGT Name	Gastrointestinal motility and defaecation conditions +
MedDRA HLGT Code	10017977 +
MedDRA SOC Name	Gastrointestinal disorders +
MedDRA SOC Code	10017947 +

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	1/16/2019 9:40:20 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	2/7/2019 10:58:39 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/11/2019 9:38:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew
Monitored	2/13/2019 12:04:05 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	3/1/2019 1:33:26 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Partial Monitored	3/1/2019 1:33:56 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Complete	3/5/2019 1:26:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	3/5/2019 5:04:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Monitored	3/6/2019 10:09:53 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12	False	- Empty -	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONSTIPATION	False	- Empty -	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONSTIPATION	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) START DATE UNKNOWN	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	Correct per source.	2/7/2019 10:58:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	Please update to unknown.	3/1/2019 1:33:26 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	START DATE IS UNKNOWN, THERE IS A NOTE FOR THIS	3/5/2019 1:26:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Data updated/provided, query closed.	3/5/2019 5:04:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	True	- Empty -	3/6/2019 10:09:53 AM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) START TIME UNKNOWN	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Correct per source.	2/7/2019 10:58:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	Please update to unknown.	3/1/2019 1:33:56 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
UNK:UNK	False	Transcription Error	3/5/2019 1:26:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	UPDATED	3/5/2019 1:26:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	Data updated/provided, query closed.	3/5/2019 5:04:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
UNK:UNK	True	- Empty -	3/6/2019 10:09:53 AM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) UNKNOWN	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Correct per source.	2/7/2019 10:58:39 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	STOP DATE UNKNOWN	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	STOP TIME UNKNOWN	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SINGLE EPISODE	False	- Empty -	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SINGLE EPISODE	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNKNOWN (LOST TO FOLLOW-UP)	False	- Empty -	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNKNOWN (LOST TO FOLLOW-UP)	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	False	- Empty -	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Please request the PI to add the relationship code to the source and update the CRF.	2/7/2019 10:58:39 PM CT	(b) (6)	CRA	001-Mathew	
POSSIBLE	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	False	updated	2/11/2019 9:38:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	Updated.	2/13/2019 12:04:05 PM CT	(b) (6)	CRA	001-Mathew	
What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CON MED GIVEN	False	- Empty -	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CON MED GIVEN	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONSTIPATION	False	Question value " updated to 'CONSTIPATION' by VTS based on DataChange editId 3243.	1/16/2019 9:40:20 AM CT	(b) (6)	Setup Administrator	001-Mathew	
CONSTIPATION	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Constipation	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Constipation	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10010774	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10010774	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Constipation	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Constipation	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10010774	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10010774	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLT Name							1
			Field				

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Gastrointestinal atonic and hypomotility disorders NEC	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Gastrointestinal atonic and hypomotility disorders NEC	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10017933	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10017933	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Gastrointestinal motility and defaecation conditions	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Gastrointestinal motility and defaecation conditions	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10017977	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10017977	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Gastrointestinal disorders	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Gastrointestinal disorders	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA SOC Code							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10017947	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10017947	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONSTIPATION_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_	False	- Empty -	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONSTIPATION_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONSTIPATION_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:38:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONSTIPATION_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_	False	- Empty -	1/16/2019 9:40:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONSTIPATION_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	False	- Empty -	2/11/2019 9:37:58 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONSTIPATION_ _MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	True	- Empty -	2/12/2019 4:15:38 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

AE-PAIN	
AE Number	13
Adverse Event	PAIN
Onset Date	B ?
Onset Time (24 Hour Clock)	B UNK:UNK HH:MM ?
Ongoing	B <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes ?
Resolved Date	?
Resolved Time (24 Hour Clock)	?
Frequency	Single Episode
Severity	Mild
Serious Event?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Outcome	Unknown (lost to follow-up)
Action taken with study product	Not Changed
Relationship to study product	Possible ?
What other action was taken in response to this adverse event?	CON MED GIVEN
Verbatim Term	PAIN
MedDRA LLT Name	Pain
MedDRA LLT Code	10033371
MedDRA PT Name	Pain
MedDRA PT Code	10033371
MedDRA HLT Name	Pain and discomfort NEC
MedDRA HLT Code	10033372
MedDRA HLGT Name	General system disorders NEC
MedDRA HLGT Code	10018073
MedDRA SOC Name	General disorders and administration site conditions
MedDRA SOC Code	10018065

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	1/16/2019 9:46:56 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	2/7/2019 10:59:44 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew
Monitored	2/13/2019 12:04:52 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	3/1/2019 1:34:57 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Partial Monitored	3/1/2019 1:35:18 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Complete	3/5/2019 1:24:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	3/5/2019 5:04:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Monitored	3/6/2019 10:10:14 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13	False	- Empty -	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PAIN	False	- Empty -	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PAIN	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) START DATE UNKNOWN	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Correct per source.	2/7/2019 10:59:44 PM CT	(b) (6)	CRA	001-Mathew	

- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001- Mathew	
- Empty -	False	Please update to unknown (incude month/year if possible).	3/1/2019 1:34:57 PM CT	(b) (6)	Clinical Data Manager (CDM)	001- Mathew	
- Empty -	False	START DATE IS UNKNOWN	3/5/2019 1:24:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	Data updated/provided, query closed.	3/5/2019 5:04:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001- Mathew	
- Empty -	True	- Empty -	3/6/2019 10:10:14 AM CT	(b) (6)	CRA	001- Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	(This item is required.) START TIME UNKNOWN	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	Correct per source.	2/7/2019 10:59:44 PM CT	(b) (6)	CRA	001- Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001- Mathew	
- Empty -	False	Please update to unknown.	3/1/2019 1:35:18 PM CT	(b) (6)	Clinical Data Manager (CDM)	001- Mathew	
UNK:UNK	False	Transcription Error	3/5/2019 1:24:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
UNK:UNK	False	UPDATED	3/5/2019 1:24:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
UNK:UNK	False	Data updated/provided, query closed.	3/5/2019 5:04:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001- Mathew	
UNK:UNK	True	- Empty -	3/6/2019 10:10:14 AM CT	(b) (6)	CRA	001- Mathew	
Ongoing							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	(This item is required.) UNKNOWN	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	Correct per source.	2/7/2019 10:59:44 PM CT	(b) (6)	CRA	001- Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001- Mathew	
Resolved Date							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	STOP DATE UNKNOWN	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	STOP TIME UNKNOWN	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SINGLE EPISODE	False	- Empty -	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SINGLE EPISODE	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

A life-threatening adverse study experience							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNKNOWN (LOST TO FOLLOW-UP)	False	- Empty -	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNKNOWN (LOST TO FOLLOW-UP)	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	False	- Empty -	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Please request the PI to add the relationship code to the source and update the CRF.	2/7/2019 10:59:44 PM CT	(b) (6)	CRA	001-Mathew	
POSSIBLE	False	updated	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	Updated.	2/13/2019 12:04:52 PM CT	(b) (6)	CRA	001-Mathew	
What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CON MED GIVEN	False	- Empty -	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CON MED GIVEN	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PAIN	False	Question value " updated to 'PAIN' by VTS based on DataChange editId 3243.	1/16/2019 9:46:56 AM CT	(b) (6)	Setup Administrator	001-Mathew	
PAIN	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Pain	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Pain	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10033371	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10033371	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Pain	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Pain	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10033371	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10033371	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Pain and discomfort NEC	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
Pain and discomfort NEC	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLT Code							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10033372	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10033372	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
General system disorders NEC	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
General system disorders NEC	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10018073	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10018073	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
General disorders and administration site conditions	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
General disorders and administration site conditions	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10018065	False	- Empty -	1/16/2019 10:50:00 AM CT	tmsystem	TBRole	001-Mathew	
10018065	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PAIN_MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_	False	- Empty -	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PAIN_MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PAIN_MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 9:44:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PAIN_MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_	False	- Empty -	1/16/2019 9:46:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PAIN_MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	False	- Empty -	2/11/2019 9:38:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PAIN_MILD_SINGLE EPISODE_N_UNKNOWN (LOST TO FOLLOW-UP)_POSSIBLE	True	- Empty -	2/12/2019 4:16:22 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** iCRF **Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** **Subject Initials:**
Subject Number: 001018 **Current Time:**

Concomitant Medications

Were any medications taken? ☒ No ☒ Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	9/13/2018 6:31:59 PM CT	(b) (6)	CRA	001-Mathew
Complete	11/19/2018 10:25:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 6:14:03 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	11/27/2018 6:14:37 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/4/2018 7:28:18 PM CT	(b) (6)	CRA	001-Mathew
Complete	1/17/2019 11:53:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/6/2019 5:19:26 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Form: Concomitant Medications							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please add conmeds given at the hospital to the ClinQuick source and eCRF.	9/13/2018 6:31:59 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	ADDED MEDS	11/19/2018 10:25:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Added.	11/27/2018 6:14:03 PM CT	(b) (6)	CRA	001-Mathew	
Group: CMYN							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please complete all conmed forms.	11/27/2018 6:14:37 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	updated	1/17/2019 11:53:22 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	N/A	Completed.	2/6/2019 5:19:26 PM CT	(b) (6)	CRA	001-Mathew	
Were any medications taken?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:39:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	11/19/2018 10:25:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	11/27/2018 6:14:03 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-ONDANSETRON

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	1	
Medication / Therapy Name	ONDANSETRON	?
Indication	Adverse Event	
Primary Medical History Term		
Primary Adverse Event Term	11-NAUSEA	
Dose	4	
Unit	Milligram	
Dose Form	Drug Delivery System	
Frequency	As needed (PRN)	
Route	Intravenous	
Was the medication/therapy taken prior to the study?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
Start Date	<input checked="" type="checkbox"/>	?
Start Time	<input checked="" type="checkbox"/>	?
Ongoing	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	?
End Date		
End Time		

Verbatim Term	ONDANSETRON	
Trade Name	ONDANSETRON	
Generic Name	ONDANSETRON	
Level 1 Code	A	
Level 1 Term	ALIMENTARY TRACT AND METABOLISM	
Level 2 Code	A04	
Level 2 Term	ANTIEMETICS AND ANTINAUSEANTS	
Level 3 Code	A04A	
Level 3 Term	ANTIEMETICS AND ANTINAUSEANTS	
Level 4 Code	A04AA	
Level 4 Term	SEROTONIN (5HT3) ANTAGONISTS	
Drug Record Number	009553	
WHODrug SEQ1	01	
WHODrug SEQ2	001	

Route for Coding	Intravenous
Indication for Coding	NAUSEA
Country for Coding	UNITED STATES

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 10:45:47 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	12/4/2018 8:18:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	12/28/2018 12:30:30 PM CT	kcheek	Clinical Data Manager (CDM)	001-Mathew
Incomplete	1/7/2019 7:37:37 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	1/7/2019 7:37:39 AM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	1/16/2019 9:49:57 AM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	2/7/2019 3:45:53 PM CT	(b) (6)	Setup Administrator	001-Mathew
Partial Monitored	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 11:18:44 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/13/2019 2:56:48 PM CT	kcheek	Clinical Data Manager (CDM)	001-Mathew
Monitored	2/13/2019 3:08:08 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	

Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

ONDANSATRON	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONDANSATRON	False	MEDICAL CODING: Please update spelling: Ondansetron and provide indication. Thanks!	12/28/2018 12:30:30 PM CT	kcheek	Clinical Data Manager (CDM)	001-Mathew	
ONDANSETRON	False	Transcription Error	1/7/2019 7:37:37 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONDANSETRON	False	UPDATED	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONDANSETRON	False	Thanks!	2/13/2019 2:56:48 PM CT	kcheek	Clinical Data Manager (CDM)	001-Mathew	
ONDANSETRON	True	- Empty -	2/13/2019 3:08:08 PM CT	(b) (6)	CRA	001-Mathew	

Indication							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	12/4/2018 8:18:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	

If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	

Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	

Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 8:18:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
11-NAUSEA	False	- Empty -	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
11-NAUSEA	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DRUG DELIVERY SYSTEM	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

DRUG DELIVERY SYSTEM	True	- Empty	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRN	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRN	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTRAVENOUS	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTRAVENOUS	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) DATE UNKNOWN	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) TIME UNKNOWN	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) UNKNOWN	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	DATE UNKNOWN	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
End Time							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:45:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	TIME UNKNOWN	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:49:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6)	prod TBMigration	001-Mathew	
ONDANSETRON	False	Question value " updated to 'ONDANSETRON' by VTS based on DataChange editId 9874.	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ONDANSETRON	True	- Empty -	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:49:57 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
ONDANSETRON	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:49:57 AM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
ONDANSETRON	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew	
A	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew	
ALIMENTARY TRACT AND METABOLISM	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew	
A04	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew	
ANTIEMETICS AND ANTINAUSEANTS	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	

- Empty -	False	- Empty -	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew	
A04A	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	

Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew	
ANTIEMETICS AND ANTINAUSEANTS	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	

Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:49:57 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
A04AA	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	

Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:49:57 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
SEROTONIN (5HT3) ANTAGONISTS	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	

Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew	
009553	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	

WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:45 PM CT	(b) (6)	CRA	001-Mathew	
001	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Intravenous	False	Question value " updated to 'Intravenous' by VTS based on DataChange editId 2443.	11/19/2018 10:45:47 AM CT	(b) (6)	Setup Administrator	001-Mathew	
Intravenous	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NAUSEA	False	Question value " updated to 'NAUSEA' by VTS based on DataChange editId 4119.	1/16/2019 9:49:57 AM CT	(b) (6)	Setup Administrator	001-Mathew	
NAUSEA	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:25:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 10:45:47 AM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	2/7/2019 10:54:01 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-SALINE

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	2
Medication / Therapy Name	SALINE
Indication	Other
If Other Indication, specify	PERIPHERAL IV SALINE LOCK FLUSH
Primary Medical History Term	
Primary Adverse Event Term	
Dose	10
Unit	Milliliter; cm3
Dose Form	Drug Delivery System
Frequency	Once
Route	Intravenous
Was the medication/therapy taken prior to the study?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Start Date	<input checked="" type="checkbox"/>
Start Time	<input checked="" type="checkbox"/>
Ongoing	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
End Date	
End Time	

Verbatim Term	SALINE
Trade Name	NORMAL SALINE
Generic Name	NORMAL SALINE
Level 1 Code	B
Level 1 Term	BLOOD AND BLOOD FORMING ORGANS
Level 2 Code	B05
Level 2 Term	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS
Level 3 Code	B05C
Level 3 Term	IRRIGATING SOLUTIONS
Level 4 Code	B05CB
Level 4 Term	SALT SOLUTIONS
Drug Record Number	000754

WHODrug SEQ1	01	
WHODrug SEQ2	006	
Route for Coding	Intravenous	
Indication for Coding	PERIPHERAL IV SALINE LOCK FLUSH	
Country for Coding	UNITED STATES	

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 10:48:02 AM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	1/16/2019 9:58:03 AM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	2/7/2019 3:45:53 PM CT	(b) (6)	Setup Administrator	001-Mathew
Partial Monitored	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 11:19:11 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/8/2019 8:36:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/8/2019 8:39:13 AM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/8/2019 1:31:12 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SALINE	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

SALINE	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Indication							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	False	- Empty -	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PERIPHERAL IV SALINE LOCK FLUST	False	- Empty -	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PERIPHERAL IV SALINE LOCK FLUST	False	Please change Flust to Flush.	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
PERIPHERAL IV SALINE LOCK FLUSH	False	Transcription Error	2/8/2019 8:36:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PERIPHERAL IV SALINE LOCK FLUSH	False	updated	2/8/2019 8:36:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PERIPHERAL IV SALINE LOCK FLUSH	True	Updated.	2/8/2019 1:31:12 PM CT	(b) (6)	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mL	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mL	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DRUG DELIVERY SYSTEM	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DRUG DELIVERY SYSTEM	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

ONCE	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONCE	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTRAVENOUS	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTRAVENOUS	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) DATE UNKNOWN	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) TIME UNKNOWN	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) UNKNOWN	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	DATE UNKNOWN	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:47:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	TIME UNKNOWN	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	

Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:58:02 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
SALINE	False	Question value " updated to 'SALINE' by VTS based on DataChange editId 9874.	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
SALINE	True	- Empty -	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:58:03 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
NORMAL SALINE	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:58:03 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
NORMAL SALINE	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew	
B	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew	
BLOOD AND BLOOD FORMING ORGANS	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew	
B05	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew	
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew	
B05C	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew	
IRRIGATING SOLUTIONS	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:58:03 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
B05CB	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:58:03 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
SALT SOLUTIONS	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew	
000754	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	

- Empty -	False	- Empty -	2/22/2019 6:52:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:51 PM CT	(b) (6)	CRA	001-Mathew	
006	True	- Empty -	2/25/2019 2:54:01 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Intravenous	False	Question value " updated to 'Intravenous' by VTS based on DataChange editId 2443.	11/19/2018 10:48:02 AM CT	(b) (6)	Setup Administrator	001-Mathew	
Intravenous	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PERIPHERAL IV SALINE LOCK FLUST	False	Question value " updated to 'PERIPHERAL IV SALINE LOCK FLUST' by VTS based on DataChange editId 4119.	1/16/2019 9:58:03 AM CT	(b) (6)	Setup Administrator	001-Mathew	
PERIPHERAL IV SALINE LOCK FLUST	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	
PERIPHERAL IV SALINE LOCK FLUSH	False	Question value 'PERIPHERAL IV SALINE LOCK FLUST' updated to 'PERIPHERAL IV SALINE LOCK FLUSH' by VTS based on DataChange editId 5533.	2/8/2019 8:39:13 AM CT	(b) (6)	Setup Administrator	001-Mathew	
PERIPHERAL IV SALINE LOCK FLUSH	True	- Empty -	2/8/2019 1:31:12 PM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:46:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 10:48:02 AM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	2/7/2019 11:03:46 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-DOCUSATE SODIUM

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	3
Medication / Therapy Name	DOCUSATE SODIUM
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	12-CONSTIPATION
Dose	100
Unit	Milligram
Dose Form	Tablet; tab
Frequency	As needed (PRN)
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Start Date	<input checked="" type="checkbox"/> <input type="checkbox"/>
Start Time	<input checked="" type="checkbox"/> <input type="checkbox"/>
Ongoing	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
End Date	
End Time	

Verbatim Term	DOCUSATE SODIUM
Trade Name	DOCUSATE SODIUM
Generic Name	DOCUSATE SODIUM
Level 1 Code	A
Level 1 Term	ALIMENTARY TRACT AND METABOLISM
Level 2 Code	A06
Level 2 Term	DRUGS FOR CONSTIPATION
Level 3 Code	A06A
Level 3 Term	DRUGS FOR CONSTIPATION
Level 4 Code	A06AA
Level 4 Term	SOFTENERS, EMOLLIENTS
Drug Record Number	000616
WHODrug SEQ1	02
WHODrug SEQ2	001

Route for Coding	Oral
Indication for Coding	CONSTIPATION
Country for Coding	UNITED STATES

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 10:49:52 AM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	1/16/2019 9:51:52 AM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	2/7/2019 3:45:53 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOCUSATE SODIUM	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOCUSATE SODIUM	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
Indication							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12-CONSTIPATION	False	- Empty -	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12-CONSTIPATION	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
100	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
100	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	

Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	

If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	

Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	

Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRN	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRN	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	

If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) DATE UNKNOWN	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	(This item is required.) TIME UNKNOWN	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001- Mathew	
Ongoing							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	(This item is required.) UNKNOWN	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001- Mathew	
End Date							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	DATE UNKNOWN	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001- Mathew	
End Time							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	11/19/2018 10:49:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	TIME UNKNOWN	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001- Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	1/16/2019 9:51:44 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001- Mathew	
Verbatim Term							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
DOCUSATE SODIUM	False	Question value " updated to 'DOCUSATE SODIUM' by VTS based on DataChange editId 9874.	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
DOCUSATE SODIUM	True	- Empty -	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:51:52 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
DOCUSATE SODIUM	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:51:52 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
DOCUSATE SODIUM	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew	
A	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew	

ALIMENTARY TRACT AND METABOLISM	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew	
A06	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew	
DRUGS FOR CONSTIPATION	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew	
A06A	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew	
DRUGS FOR CONSTIPATION	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:51:52 AM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
A06AA	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:51:52 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001-Mathew	
SOFTENERS, EMOLLIENTS	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew	
000616	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew	
02	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:52:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:36 PM CT	(b) (6)	CRA	001-Mathew	
001	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 2443.	11/19/2018 10:49:52 AM CT	(b) (6)	Setup Administrator	001-Mathew	

Oral	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001- Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
CONSTIPATION	False	Question value " updated to 'CONSTIPATION' by VTS based on DataChange editId 4119.	1/16/2019 9:51:52 AM CT	(b) (6)	Setup Administrator	001- Mathew	
CONSTIPATION	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001- Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:48:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 10:49:52 AM CT	(b) (6)	Setup Administrator	001- Mathew	
UNITED STATES	True	- Empty -	2/7/2019 11:01:02 PM CT	(b) (6)	CRA	001- Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-ACETAMINOPHEN

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	4
Medication / Therapy Name	ACETAMINOPHEN
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	13-PAIN
Dose	500
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Other
If Other Frequency, specify	Every 4 hours
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
Start Date	<input checked="" type="radio"/> B ?
Start Time	<input checked="" type="radio"/> B ?
Ongoing	<input checked="" type="radio"/> B <input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
End Date	
End Time	

Verbatim Term	ACETAMINOPHEN
Trade Name	ACETAMINOPHEN
Generic Name	ACETAMINOPHEN
Level 1 Code	N
Level 1 Term	NERVOUS SYSTEM
Level 2 Code	N02
Level 2 Term	ANALGESICS
Level 3 Code	N02B
Level 3 Term	OTHER ANALGESICS AND ANTIPYRETICS
Level 4 Code	N02BE
Level 4 Term	ANILIDES
Drug Record Number	000200
WHODrug SEQ1	01

WHODrug SEQ2	009	
Route for Coding	Oral	
Indication for Coding	PAIN	
Country for Coding	UNITED STATES	

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 10:52:02 AM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	1/16/2019 9:53:27 AM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	2/7/2019 3:45:53 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ACETAMINOPHEN	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Indication							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13-PAIN	False	- Empty -	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13-PAIN	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
500	False	- Empty -	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

500	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

Q4H	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Q4H	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) DATE UNKNOWN	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) TIME UNKNOWN	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) UNKNOWN	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	DATE UNKNOWN	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:52:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	TIME UNKNOWN	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:53:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
ACETAMINOPHEN	False	Question value " updated to 'ACETAMINOPHEN' by VTS based on DataChange editId 9874.	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:53:27 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:53:27 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew	
N	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	

- Empty -	False	- Empty -	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew	
NERVOUS SYSTEM	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew	
N02	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew	
ANALGESICS	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew	
N02B	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew	
OTHER ANALGESICS AND ANTIPYRETICS	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 9:53:27 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
N02BE	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:53:27 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
ANILIDES	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew	
000200	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:32 PM CT	(b) (6)	CRA	001-Mathew	
009	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 2443.	11/19/2018 10:52:02 AM CT	(b) (6)	Setup Administrator	001-Mathew	
Oral	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PAIN	False	Question value " updated to 'PAIN' by VTS based on DataChange editId 4119.	1/16/2019 9:53:27 AM CT	(b) (6)	Setup Administrator	001-Mathew	
PAIN	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:50:04 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 10:52:02 AM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	2/7/2019 11:01:47 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001018
Subject Number: 001018

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-MAGNESIUM HYDROXIDE

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	5
Medication / Therapy Name	MAGNESIUM HYDROXIDE
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	12-CONSTIPATION
Dose	30
Unit	Milliliter; cm3
Dose Form	Liquid
Frequency	As needed (PRN)
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Start Date	<input checked="" type="checkbox"/>
Start Time	<input checked="" type="checkbox"/>
Ongoing	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
End Date	
End Time	

Verbatim Term	MAGNESIUM HYDROXIDE
Trade Name	MAGNESIUM HYDROXIDE
Generic Name	MAGNESIUM HYDROXIDE
Level 1 Code	A
Level 1 Term	ALIMENTARY TRACT AND METABOLISM
Level 2 Code	A06
Level 2 Term	DRUGS FOR CONSTIPATION
Level 3 Code	A06A
Level 3 Term	DRUGS FOR CONSTIPATION
Level 4 Code	A06AD
Level 4 Term	OSMOTICALLY ACTING LAXATIVES
Drug Record Number	001232
WHODrug SEQ1	01
WHODrug SEQ2	001

Route for Coding	Oral
Indication for Coding	CONSTIPATION
Country for Coding	UNITED STATES

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 10:55:57 AM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	1/16/2019 9:55:13 AM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	2/7/2019 3:45:54 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MAGNESIUM HYDROXIDE	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MAGNESIUM HYDROXIDE	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Indication							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12-CONSTIPATION	False	- Empty -	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12-CONSTIPATION	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
30	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
30	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	

Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mL	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mL	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	

If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	

Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LIQUID	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LIQUID	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	

Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRN	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRN	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	

If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) DATE UNKNOWN	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	(This item is required.) TIME UNKNOWN	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001- Mathew	
Ongoing							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	(This item is required.) UNKNOWN	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	Correct per source.	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001- Mathew	
End Date							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	DATE UNKNOWN	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001- Mathew	
End Time							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	11/19/2018 10:55:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	TIME UNKNOWN	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001- Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	1/16/2019 9:55:08 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001- Mathew	
Verbatim Term							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
MAGNESIUM HYDROXIDE	False	Question value " updated to 'MAGNESIUM HYDROXIDE' by VTS based on DataChange editId 9874.	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
MAGNESIUM HYDROXIDE	True	- Empty -	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:55:13 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
MAGNESIUM HYDROXIDE	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:55:13 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
MAGNESIUM HYDROXIDE	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew	
A	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew	
ALIMENTARY TRACT AND METABOLISM	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew	
A06	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew	
DRUGS FOR CONSTIPATION	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew	
A06A	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew	
DRUGS FOR CONSTIPATION	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 9:55:13 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
A06AD	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 9:55:13 AM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
OSMOTICALLY ACTING LAXATIVES	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew	
001232	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:47:41 PM CT	(b) (6)	CRA	001-Mathew	
001	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 2443.	11/19/2018 10:55:57 AM CT	(b) (6)	Setup Administrator	001-Mathew	
Oral	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONSTIPATION	False	Question value " updated to 'CONSTIPATION' by VTS based on DataChange editId 4119.	1/16/2019 9:55:13 AM CT	(b) (6)	Setup Administrator	001-Mathew	
CONSTIPATION	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:52:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 10:55:57 AM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	2/7/2019 11:02:27 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	Unscheduled 1
Visit Date	26/JUL/2018 DD/MON/YYYY (EN)
Visit Number	
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
Complete	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:16:21 PM CT	(b) (6)	Setup Administrator	001-Mathew
Partial Monitored	12/18/2018 2:16:44 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:53:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 11:29:08 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
Unscheduled 1	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Unscheduled 1	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
26/JUL/2018	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:16:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:29:08 AM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:16:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/10/2019 11:29:08 AM CT	(b) (6)	CRA	001- Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001- Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001- Mathew	
Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001- Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001- Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001- Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001- Mathew	

Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	

Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	

Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	

Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	9/14/2018 11:02:31 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:25:46 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Unscheduled 1 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		26/JUL/2018 DD/MON/YYYY(EN)		
Time of Measurements (24 Hour Clock)		07:51 HH:MM		
Not Done	Result	Test Name	Unit	Clinical Significance
<input checked="" type="checkbox"/>		Temperature	F	NCS CS
<input type="checkbox"/>	86	Heart Rate	beats/min	NCS CS
<input checked="" type="checkbox"/>		Respiratory Rate	breaths/min	NCS CS
<input type="checkbox"/>	148	Systolic Blood Pressure	mmHg	NCS CS
<input type="checkbox"/>	B 97 ?	Diastolic Blood Pressure	mmHg	NCS CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Monitored	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Incomplete	12/18/2018 4:22:01 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:53:42 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:03:17 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

26/JUL/2018	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Time of Measurements (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:51	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:51	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

cm	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

BMI	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

86	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
86	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Result							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
148	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
148	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
97	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
97	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
97	False	(Diastolic Blood Pressure should be between 40-95, inclusively.) correct as is	12/19/2018 1:53:42 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
97	True	Correct as entered.	1/10/2019 3:03:17 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:02:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NCS	False	- Empty -	9/14/2018 11:03:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NCS	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NCS	True	- Empty -	10/15/2018 3:25:58 PM CT	(b) (6)	CRA	001-Mathew	
NCS	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	Unscheduled 2
Visit Date	26/JUL/2018 DD/MON/YYYY (EN)
Visit Number	
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
Complete	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:16:21 PM CT	(b) (6)	Setup Administrator	001-Mathew
Partial Monitored	12/18/2018 2:16:50 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:53:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 11:29:13 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
Unscheduled 2	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Unscheduled 2	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
26/JUL/2018	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:16:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:29:13 AM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:16:50 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/10/2019 11:29:13 AM CT	(b) (6)	CRA	001- Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001- Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001- Mathew	
Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001- Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001- Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001- Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001- Mathew	

Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	

Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	

Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	

Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	9/14/2018 11:03:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/15/2018 3:26:18 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Unscheduled 2 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		26/JUL/2018 DD/MON/YYYY(EN)		
Time of Measurements (24 Hour Clock)		07:58 HH:MM		
Not Done	Result	Test Name	Unit	Clinical Significance
<input checked="" type="checkbox"/>		Temperature	F	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	93	Heart Rate	beats/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input checked="" type="checkbox"/>		Respiratory Rate	breaths/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	135	Systolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	93	Diastolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Monitored	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Time of Measurements (24 Hour Clock)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:58	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:58	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	

Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
93	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
93	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	

Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	

Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	

Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
135	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
135	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	

Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
93	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
93	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/14/2018 11:03:56 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/14/2018 11:04:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/15/2018 3:26:26 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	Unscheduled 3
Visit Date	17/JUL/2018 DD/MON/YYYY (EN)
Visit Number	
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
Complete	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:16:21 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:53:48 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 11:54:23 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
Unscheduled 3	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Unscheduled 3	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
17/JUL/2018	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
Y	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:16:21 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:54:23 AM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	10/19/2018 10:30:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	11/27/2018 5:48:17 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Unscheduled 3 **iCRF Status:** Signed Locked
Subject Caption: 001018 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001018 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		17/JUL/2018 DD/MON/YYYY(EN)		
Time of Measurements (24 Hour Clock)		11:54 HH:MM		
Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>				<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>				<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input checked="" type="checkbox"/>		Temperature	F	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	77	Heart Rate	beats/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input checked="" type="checkbox"/>		Respiratory Rate	breaths/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	143	Systolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	94	Diastolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:33:54 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Time of Measurements (24 Hour Clock)							1
Field							

Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
11:54	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
11:54	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

kg	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
77	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
77	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

HR	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
143	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
143	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
94	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

94	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/19/2018 10:30:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 10:30:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/27/2018 5:48:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration



Below list includes all users that have or had signature permissions. Each row indicates the effective date range for the username and full name combination. Blank dates in the “To” column signify electronic signature was still in effect as of the date the PDF was generated.

Electronic Signature Manifestations				
User	From	To	Full Name	Signature Meaning
DLG	11/JAN/2019 11:41:35 CT		Allen Hunt	By providing my electronic signature, I certify that I have reviewed the data.

All timestamps in this report are in (GMT-06:00) Central Time (US & Canada) timezone.

Patient CaseBook requested by User: "jbailey" in role: "View Only"

Trial: VLN, Version: MSC006
Site: 001-Mathew

Patient Type: Patient
Patient: 001023

Version Date: 02/22/2019
Date Generated:03/31/2019

Subject Information	
Subject Number	001023
Informed Consent Date	17/JUL/2018 DD/MON/YYYY(EN)
Protocol Number	Original
Subject Type	Non-menthol Smoker
Randomization Number	001-043
Assigned Product	Non-menthol VLN
Re-Consent Date	
Protocol Amendment Number Re-consent	Informed Re-Consent Date
Amendment 2	31/JUL/2018 DD/MON/YYYY(EN)
Amendment 2	12/SEP/2018 DD/MON/YYYY(EN)

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
Complete	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/29/2018 3:12:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/4/2018 1:30:40 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	9/28/2018 10:30:40 AM CT	(b) (6)	CRA	001-Mathew
Complete	10/1/2018 2:15:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew

Monitored	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Complete	12/19/2018 1:58:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/21/2018 1:14:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	1/10/2019 3:28:44 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	2/7/2019 3:51:19 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	2/8/2019 6:21:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/12/2019 2:53:24 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	2/18/2019 4:35:08 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	2/23/2019 3:43:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/24/2019 5:13:58 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Subject Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
43	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001043	False	Recording Error	8/29/2018 3:12:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001023	False	Recording Error	9/4/2018 1:30:40 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001023	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	

Informed Consent Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
17/JUL/2018	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	

Protocol Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

ORIGINAL	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORIGINAL	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Subject Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
NON-MENTHOL SMOKER	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL SMOKER	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Randomization Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
43	False	Transcription Error	12/21/2018 1:14:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001-043	False	Transcription Error	2/8/2019 6:21:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001-043	True	- Empty -	2/12/2019 2:53:24 PM CT	(b) (6)	CRA	001-Mathew	
Randomization Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Assigned Product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
NON-MENTHOL VLN	False	Transcription Error	12/21/2018 1:14:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	True	- Empty -	1/10/2019 3:28:44 PM CT	(b) (6)	CRA	001-Mathew	
Active							1
	Field						

Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
YES	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YES	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Enrolled							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
YES	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YES	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Enroll Date							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
17/JUL/2018	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Dropped							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Registration Date							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Subject Initials							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	

Subject Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
43	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001043	False	- Empty -	8/29/2018 3:12:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001023	False	- Empty -	9/4/2018 1:30:40 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
001023	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Country							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNITED STATES	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Group: Re-Consent Date							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please add re-consent date of 12-Sep-2018 under amendment 2.	9/28/2018 10:30:40 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	added	10/1/2018 2:15:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Added.	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Protocol Amendment Number Re-consent							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
AMENDMENT 2	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMENDMENT 2	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Informed Re-Consent Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
31/JUL/2018	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

31/JUL/2018	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Protocol Amendment Number Re-consent							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
AMENDMENT 2	False	- Empty -	10/1/2018 2:15:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMENDMENT 2	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	
Informed Re-Consent Date							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
12/SEP/2018	False	- Empty -	10/1/2018 2:15:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	True	- Empty -	10/16/2018 12:35:17 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit Name	Screening
Visit Date	17/JUL/2018 DD/MON/YYYY(EN)
Visit Number	1
Was tobacco cessation information provided?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:28:49 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:58:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 10:22:30 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Screening	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Screening	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
Visit Type							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	

Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	

Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	

Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	

Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	

Upcoming Visit Offset							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:28:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 10:22:30 AM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:28:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 10:22:30 AM CT	(b) (6)	CRA	001-Mathew	

Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/23/2018 1:33:51 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:39:13 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:28:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 10:22:30 AM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Inclusion / Exclusion Criteria Not Met

Met All Eligibility Criteria? ☒ No ☒ Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:33:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:49:31 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Met All Eligibility Criteria?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 1:33:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Criterion Identifier							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Criterion							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Criterion Text 201-400 (Hidden)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Criterion Text 401-600 (Hidden)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Criterion Text 601-800 (Hidden)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:33:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Inclusion/Exclusion Category							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/23/2018 1:33:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag used to create form only once.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	8/23/2018 1:33:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	10/16/2018 12:49:31 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		17/JUL/2018 DD/MON/YYYY(EN)		
Time of Measurements (24 Hour Clock)		12:35 HH:MM		
Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>	161	Height	cm	
<input type="checkbox"/>	62.6	Weight	kg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	24.2	Body Mass Index	kg/m2	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	98.3	Temperature	F	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	64	Heart Rate	beats/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	16	Respiratory Rate	breaths/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	111	Systolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	76	Diastolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Incomplete	10/7/2018 10:12:33 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Partial Monitored	12/18/2018 2:28:55 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:58:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 10:39:20 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Time of Measurements (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12:35	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12:35	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
161	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
161	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
	Field						

Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 10:12:33 PM CT	(b) (6)	Setup Administrator	001-Mathew	
NCS	False	Transcription Error	10/8/2018 6:15:18 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NCS	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
NCS	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:28:55 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 10:39:20 AM CT	(b) (6)	CRA	001-Mathew	
Not Done							2
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
62.6	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
62.6	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
24.2	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

24.2	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.3	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.3	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	

Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
64	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
64	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
111	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
111	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
76	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
76	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:34:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:18 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Electrocardiogram

Was the ECG performed? ☒ No ☒ Yes

Date of ECG B 17/JUL/2018
DD/MON/YYYY(EN)

Time of ECG (24 hour clock) 12:56
HH:MM

Overall ECG Clinical Significance ☒ Normal ☒ Abnormal, Not Clinically Significant ☒ Abnormal, Clinically Significant

ECG Test Name	Test Results	Units
Heart Rate	63	Beats per Minute
RR	960	Millisecond
PR	150	Millisecond
QT	B 422	Millisecond
QRS	84	Millisecond
QTcF	429	Millisecond

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	8/28/2018 5:15:19 PM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	11/9/2018 10:16:41 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Complete	12/19/2018 1:58:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the ECG performed? 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	

What was the planned time point of the measurement? 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Screening	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Screening	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	

Date of ECG 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

17/JUL/2018	False	(Date of ECG should be equal to or after the Screening visit date and 1 day prior to the Day -1 visit date.) correct as is	12/19/2018 1:58:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	Correct as entered.	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Time of ECG (24 hour clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12:56	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12:56	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Overall ECG Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
If Abnormal, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ECG MEAN HEART RATE	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ECG MEAN HEART RATE	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							1
Field							

Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
63	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
63	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EGHRMN	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EGHRMN	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							2
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) RR DURATION	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) RR DURATION	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							2
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
960	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
960	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Units							2

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RRMEAN	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RRMEAN	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) PR DURATION	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) PR DURATION	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
150	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
150	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	

Test Code								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
PRMEAN	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
PRMEAN	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew		
ECG Test Name								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
SUMMARY (MEAN) QT DURATION	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
SUMMARY (MEAN) QT DURATION	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew		
Test Results								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
422	False	(QT Interval should be between 240-420 msec (inclusive).) CORRECT AS IS	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
422	False	Site indicates data is correct as is.	11/9/2018 10:16:41 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew		
422	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew		
Units								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
msec	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
msec	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								4
	Field							

Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTMEAN	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTMEAN	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							5
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) QRS DURATION	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) QRS DURATION	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							5
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
84	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
84	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QRS DUR	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QRS DUR	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTcF - Fridericia's Correction Formula	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTcF - Fridericia's Correction Formula	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
429	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
429	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:36:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:30:16 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Tobacco/Nicotine Product Use History

Not Done ☐

Duration of Cigarette Use 28

Unit for Duration of Cigarette Use Years

Typical Number of Cigarettes Smoked Per Day 20

Usual Brand MARLBORO

Usual Brand Style GOLD

Usual Brand Flavor NON-MENTHOL

Usual Brand Size KING

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:37:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:31:33 PM CT	(b) (6)	CRA	001-Mathew
Complete	11/6/2018 7:24:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/3/2018 1:49:48 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/17/2018 11:56:38 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Complete	12/17/2018 1:31:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/19/2018 4:12:22 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Monitored	1/10/2019 3:29:24 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:37:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	10/16/2018 12:31:33 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:37:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:31:33 PM CT	(b) (6)	CRA	001-Mathew	
Duration of Cigarette Use							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
28	False	- Empty -	8/23/2018 1:37:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
28	True	- Empty -	10/16/2018 12:31:33 PM CT	(b) (6)	CRA	001-Mathew	
Unit for Duration of Cigarette Use							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YEARS	False	- Empty -	8/23/2018 1:37:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YEARS	True	- Empty -	10/16/2018 12:31:33 PM CT	(b) (6)	CRA	001-Mathew	
Typical Number of Cigarettes Smoked Per Day							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20	False	- Empty -	8/23/2018 1:37:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
20	True	- Empty -	10/16/2018 12:31:33 PM CT	(b) (6)	CRA	001-Mathew	
Usual Brand							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MARLBORO	False	- Empty -	8/23/2018 1:37:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

MARLBORO	True	- Empty -	10/16/2018 12:31:33 PM CT	(b) (6)	CRA	001-Mathew	
Usual Brand Style							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GOLD	False	- Empty -	8/23/2018 1:37:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GOLD	True	- Empty -	10/16/2018 12:31:33 PM CT	(b) (6)	CRA	001-Mathew	
Usual Brand Flavor							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON MENTHOL	False	- Empty -	8/23/2018 1:37:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON MENTHOL	True	- Empty -	10/16/2018 12:31:33 PM CT	(b) (6)	CRA	001-Mathew	
NON MENTHOL	False	hyphenate as NON-MENTHOL	12/17/2018 11:56:38 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
NON-MENTHOL	False	updated	12/17/2018 1:31:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL	False	Transcription Error	12/17/2018 1:31:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL	False	Update made. Query closed.	12/19/2018 4:12:22 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
NON-MENTHOL	True	- Empty -	1/10/2019 3:29:24 PM CT	(b) (6)	CRA	001-Mathew	
Usual Brand Size							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
85MM	False	- Empty -	8/23/2018 1:37:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
85MM	True	- Empty -	10/16/2018 12:31:33 PM CT	(b) (6)	CRA	001-Mathew	
KING	False	Transcription Error	11/6/2018 7:24:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
KING	True	- Empty -	12/3/2018 1:49:48 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

VLN Product Trial +

Number of cigarettes smoked 2 +

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:37:17 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:39:22 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Number of cigarettes smoked							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	False	- Empty -	8/23/2018 1:37:17 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	10/16/2018 12:39:22 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Urine Cotinine Screen

Was the Urine Cotinine sample collected?

☒ No ☒ Yes

Date of Collection

17/JUL/2018
 DD/MON/YYYY
 (EN)

Is result positive for urine cotinine (greater than or equal to 500 ng/mL)?

☒ No ☒ Yes

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:37:28 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:32:40 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the Urine Cotinine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 1:37:28 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:32:40 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 1:37:28 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

17/JUL/2018	True	- Empty -	10/16/2018 12:32:40 PM CT	(b) (6)	CRA	001-Mathew	
Is result positive for urine cotinine (greater than or equal to 500 ng/mL)?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 1:37:28 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:32:40 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Medical History

Has the subject experienced any past and/or concomitant medical conditions, significant past medical history or past surgeries?

☒ No ☒ Yes

MH Number	Reported Term	Unknown Start Date	Onset Date	Ongoing?	End Date
1	HYSTERECTOMY	<input type="checkbox"/>	UNK/UNK/1995 DD/MON/YYYY (EN)	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes	UNK/UNK/1995 DD/MON/YYYY (EN)
2	ABNORMAL MENSTRUAL BLEEDING	<input type="checkbox"/>	UNK/UNK/1995 DD/MON/YYYY (EN)	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes	UNK/UNK/1995 DD/MON/YYYY (EN)
3	SURGERY TO REPLACE RIGHT THUMB JOINT	<input type="checkbox"/>	UNK/MAR/1999 DD/MON/YYYY (EN)	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes	UNK/MAR/1999 DD/MON/YYYY (EN)
4	SURGERY TO REPAIR RIGHT CARPAL TUNNEL SYNDROME	<input type="checkbox"/>	UNK/UNK/1997 DD/MON/YYYY (EN)	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes	UNK/UNK/1997 DD/MON/YYYY (EN)
5	CARPAL TUNNEL SYNDROME	<input type="checkbox"/>	UNK/UNK/1997 DD/MON/YYYY (EN)	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes	UNK/UNK/1997 DD/MON/YYYY (EN)

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew
Complete	11/27/2018 2:08:10 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:47:10 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Has the subject experienced any past and/or concomitant medical conditions, significant past medical history or past surgeries?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
MH Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Reported Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HYSTERECTOMY	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HYSTERECTOMY	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Unknown Start Date							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/7/2019 3:23:08 PM CT	(b) (6) prod	TBMigration	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1995	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1995	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1995	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1995	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
MH Number							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
2	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Reported Term							2
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

		tored?					
ABNORMAL MENSTRUAL BLEEDING		False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
ABNORMAL MENSTRUAL BLEEDING		True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew
Unknown Start Date							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/7/2019 3:23:08 PM CT	(b) (6) prod	TBMigration	001-Mathew	
Onset Date							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/UNK/1995	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1995	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing?							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
End Date							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/UNK/1995	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1995	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
MH Number							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
3	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Reported Term							3
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
SURGERY TO REPLACE RIGHT THUMB JOINT	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SURGERY TO REPLACE RIGHT THUMB JOINT	False	Please add the medical history which led to the replacement of the right thumb joint to the source and eCRF.	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
SURGERY TO REPLACE RIGHT THUMB JOINT	False	subject is lost to follow up and could not be contacted	11/27/2018 2:08:10 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SURGERY TO REPLACE RIGHT THUMB JOINT	True	Subject is lost to follow-up and cannot clarify the reason for surgery.	12/4/2018 7:47:10 PM CT	(b) (6)	CRA	001-Mathew	
Unknown Start Date							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/7/2019 3:23:08 PM CT	(b) (6) prod	TBMigration	001-Mathew	
Onset Date							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/MAR/1999	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/MAR/1999	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing?							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
End Date							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/MAR/1999	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/MAR/1999	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
MH Number							4

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
4	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Reported Term							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
SURGERY TO REPAIR RIGHT CARPAL TUNNEL SYNDROME	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SURGERY TO REPAIR RIGHT CARPAL TUNNEL SYNDROME	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Unknown Start Date							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/7/2019 3:23:08 PM CT	(b) (6) prod	TBMigration	001-Mathew	
Onset Date							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/UNK/1997	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1997	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing?							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
N	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
End Date							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/UNK/1997	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

UNK/UNK/1997	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
MH Number							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
5	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Reported Term							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
CARPAL TUNNEL SYNDROME	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CARPAL TUNNEL SYNDROME	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Unknown Start Date							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/7/2019 3:23:08 PM CT	(b) (6) prod	TBMigration	001-Mathew	
Onset Date							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/UNK/1997	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1997	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing?							5
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
N	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	
End Date							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
UNK/UNK/1997	False	- Empty -	8/23/2018 1:40:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK/UNK/1997	True	- Empty -	10/16/2018 12:30:44 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Serology (HIV, HBsAg, HCV)

Was the Serology sample collected? ☒ No ☒ Yes

Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:41:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:32:29 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the Serology sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 1:41:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:32:29 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 1:41:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/16/2018 12:32:29 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Pregnancy Test

Was the pregnancy test performed? ☒ No ☒ Yes
Date of Collection 17/JUL/2018 DD/MON/YYYY(EN)
Test Type Serum
Pregnancy Test Result ☒ Negative ☒ Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/9/2018 1:17:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:32:48 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the pregnancy test performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	10/9/2018 1:17:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:32:48 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not performed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/9/2018 1:17:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:48 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	10/9/2018 1:17:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/16/2018 12:32:48 PM CT	(b) (6)	CRA	001-Mathew	
Test Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SERUM	False	- Empty -	10/9/2018 1:17:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SERUM	True	- Empty -	10/16/2018 12:32:48 PM CT	(b) (6)	CRA	001-Mathew	
Pregnancy Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	10/9/2018 1:17:37 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:32:48 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Physical Examination - Full

Was the Physical Examination performed?

☒ No ☒ Yes

Date of Examination

17/JUL/2018
DD/MON/YYYY(EN)

Body System	If Other, specify	Result	Specify if Abnormal or Not Done	Specify Clinical Significance if Abnormal
General Appearance		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
HEENT		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Thyroid (Endocrine)		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Heart		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Chest		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Lungs		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Abdomen		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Skin		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Neurological		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Extremities		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Back/Neck		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Lymph Nodes		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
Musculoskeletal		Normal		<input checked="" type="checkbox"/> NCS <input checked="" type="checkbox"/> CS

Oral Cavity	+	+	Normal	+	NCS	CS	+
Oropharynx	+	+	Normal	+	NCS	CS	+
Other	+	DENTITION	Normal	+	NCS	CS	+

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the Physical Examination performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not performed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	

Date of Examination								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
17/JUL/2018	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
17/JUL/2018	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew		

Body System								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
GENERAL APPEARANCE	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
GENERAL APPEARANCE	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew		

If Other, specify								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew		

Result								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew		

Specify if Abnormal or Not Done								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		

- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEENT	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEENT	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
THYROID (ENDOCRINE)	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
THYROID (ENDOCRINE)	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEART	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEART	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CHEST	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CHEST	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							5

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LUNGS	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LUNGS	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	

Specify if Abnormal or Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ABDOMEN	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ABDOMEN	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SKIN	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SKIN	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEUROLOGICAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEUROLOGICAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EXTREMITIES	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EXTREMITIES	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							10
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BACK/NECK	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BACK/NECK	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							11

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LYMPH NODES	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LYMPH NODES	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	

Result							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MUSCULOSKELETAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MUSCULOSKELETAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL CAVITY	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL CAVITY	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OROPHARYNX	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OROPHARYNX	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Body System							16
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							16
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DENTITION	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DENTITION	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							16
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify if Abnormal or Not Done							16
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	
Specify Clinical Significance if Abnormal							16
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:41:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:32:01 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Demographics	
Date of Birth	(b) (6) DD/MON/YYYY(EN)
Gender	Female
Age	50
Reproductive Status	Surgically Sterile
Ethnicity	Not Hispanic or Latino
Race	White/Caucasian

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:28:52 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Date of Birth							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
(b) (6)	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
(b) (6)	True	- Empty -	10/16/2018 12:28:52 PM CT	(b) (6)	CRA	001-Mathew	
Gender							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

F	True	- Empty -	10/16/2018 12:28:52 PM CT	(b) (6)	CRA	001-Mathew	
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Age							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
50	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
50	True	- Empty -	10/16/2018 12:28:52 PM CT	(b) (6)	CRA	001-Mathew	

Age Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YEARS	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
YEARS	True	- Empty -	10/16/2018 12:28:52 PM CT	(b) (6)	CRA	001-Mathew	

Reproductive Status							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SURGICALLY STERILE	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SURGICALLY STERILE	True	- Empty -	10/16/2018 12:28:52 PM CT	(b) (6)	CRA	001-Mathew	

Ethnicity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT HISPANIC OR LATINO	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT HISPANIC OR LATINO	True	- Empty -	10/16/2018 12:28:52 PM CT	(b) (6)	CRA	001-Mathew	

Race							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

WHITE/CAUCASIAN	False	- Empty	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WHITE/CAUCASIAN	True	- Empty	10/16/2018 12:28:52 PM CT	(b) (6)	CRA	001-Mathew	
If Other, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:28:52 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Exhaled CO Measurement

Were exhaled CO measurements performed? ☒ No ☒ Yes

Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)

Exhaled CO measurement (ppm) 33

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:42:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:32:11 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Were exhaled CO measurements performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 1:42:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:32:11 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 1:42:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/16/2018 12:32:11 PM CT	(b) (6)	CRA	001-Mathew	
Exhaled CO measurement (ppm)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
33	False	- Empty -	8/23/2018 1:42:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
33	True	- Empty -	10/16/2018 12:32:11 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Screening **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 17/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected? <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
Date of Collection	17/JUL/2018 DD/MON/YYYY(EN)
Test Name	Result
Opiates	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Amphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cocaine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cannabinoids	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Alcohol	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Methamphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/7/2018 10:12:17 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:15:00 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the Urine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/JUL/2018	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Result							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	

Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	

Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	

Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NEGATIVE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/23/2018 1:42:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	Question value " updated to 'ALCOHOL' by VTS based on DataChange editId 2348.	10/7/2018 10:12:17 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPHETAMINE	False	Question value " updated to 'METHAMPHETAMINE' by VTS based on DataChange, StateChange editId 2308.	10/7/2018 10:12:17 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPHETAMINE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NEGATIVE	False	- Empty -	10/8/2018 6:15:00 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPH	False	Question value " updated to 'METHAMPH' by VTS based on DataChange editId 2348.	10/7/2018 10:12:17 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPH	True	- Empty -	10/16/2018 12:32:36 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Chemistry

Accession Number 18389786S
Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)
Time of Collection 13:02
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Albumin	4.6	g/dL	3.9	5		Yes No Recheck				
Alkaline Phosphatase	91	U/L	37	115		Yes No Recheck				
Alanine Aminotransferase	27	U/L	10	67		Yes No Recheck				
Aspartate Aminotransferase	24	U/L	14	48		Yes No Recheck				
Bilirubin	.8	mg/dL	.2	1.6		Yes No Recheck				
Carbon Dioxide	30.5	mmol/L	24	33.2		Yes No Recheck				
Creatinine	.59	mg/dL	.5	.9		Yes No Recheck				
Glucose	88	mg/dL	73	105		Yes No Recheck				
Potassium	4.9	mEq/L	3.7	5.2		Yes No Recheck				
Protein	7.0	g/dL	6.3	8.1		Yes No Recheck				
Sodium	143	mEq/L	135	143		Yes No Recheck				
Urea Nitrogen	7	mg/dL	6	17		Yes No Recheck				
Uric Acid	4.2	mg/dL	2.3	5.9		Yes No Recheck				

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:42 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Category							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CHEM	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CHEM	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18389786S	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18389786S	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17/JUL/2018	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17/JUL/2018	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

13:02	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
13:02	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
ALB	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
ALB	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Albumin	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Albumin	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.6	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.6	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.9	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
ALP	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
ALP	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Alkaline Phosphatase	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Alkaline Phosphatase	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
91	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
91	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Units								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

U/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
U/L	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
37	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
37	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
115	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
115	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
ALT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
ALT	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Alanine Aminotransferase	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Alanine Aminotransferase	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
27	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
27	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	

Units								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
U/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
U/L	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
10	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
10	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
67	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
67	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 1								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
AST	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
AST	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Aspartate Aminotransferase	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Aspartate Aminotransferase	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
24	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
24	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
U/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
U/L	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
14	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
14	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
48	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
48	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 1								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 3								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
BILI	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
BILI	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

Bilirubin	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Bilirubin	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.8	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.8	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.2	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.6	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.6	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CO2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CO2	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	

Test Name								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Carbon Dioxide	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Carbon Dioxide	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
30.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
30.5	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Units								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
mmol/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
mmol/L	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
24	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
24	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
33.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
33.2	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CREAT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CREAT	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Creatinine	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Creatinine	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.59	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.59	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Units							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.9	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Flag							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
GLUC	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
GLUC	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Glucose	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Glucose	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
88	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
88	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
73	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
73	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
105	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
105	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
K	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
K	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Potassium	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Potassium	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.9	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mEq/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mEq/L	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

3.7	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.7	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.2	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PROT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PROT	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Protein	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Protein	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.0	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
6.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
6.3	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
8.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
8.1	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 1								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
SODIUM	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
SODIUM	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Sodium	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Sodium	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
143	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
143	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Units							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mEq/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mEq/L	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
135	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
135	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
143	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
143	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 3								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
UEAN	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
UEAN	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Urea Nitrogen	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Urea Nitrogen	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

7	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Units							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
6	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
6	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
URATE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
URATE	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Uric Acid	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Uric Acid	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	

Test Result								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
4.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
4.2	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Units								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
mg/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
mg/dL	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
2.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
2.3	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
5.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
5.9	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:27 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b)(6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b)(6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b)(6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b)(6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b)(6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b)(6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b)(6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Hematology

Accession Number 18389789B
Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)
Time of Collection 13:03
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Basophils	0.0	Thou/uL	0	.1		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Basophils/Leukocytes	.2	%	0	2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Eosinophils	.1	Thou/uL	0	.5		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Eosinophils/Leukocytes	1.3	%	.5	7.4		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Hematocrit	43.5	%	35.3	47		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Hemoglobin	14.1	g/dL	12	15.9		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Lymphocytes	2.6	Thou/uL	1.1	3.2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Lymphocytes/Leukocytes	28.3	%	15.8	45.8		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Monocytes	.4	Thou/uL	.3	.9		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Monocytes/Leukocytes	4.5	%	4.9	12.8	L	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Neutrophils	5.9	Thou/uL	1.6	7.7		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Neutrophils/Leukocytes	65.6	%	38.4	74.2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Platelets	299	Thou/uL	155	361		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Erythrocytes	4.86	Mil/uL	3.95	5.21		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Leukocytes	9.0	Thou/uL	3.7	11.5		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:42 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HEME	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HEME	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18389789B	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18389789B	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17/JUL/2018	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17/JUL/2018	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
13:03	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

13:03	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
BASO	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
BASO	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Basophils	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Basophils	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
0.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0.0	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

0	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.1	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
BASOLE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
BASOLE	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Basophils/Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Basophils/Leukocytes	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.2	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
2	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
EOS	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
EOS	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Eosinophils	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Eosinophils	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.1	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
EOSLE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
EOSLE	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Eosinophils/Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Eosinophils/Leukocytes	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.3	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.4	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.4	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HCT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HCT	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hematocrit	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hematocrit	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
43.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
43.5	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
35.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
35.3	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
47	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
47	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HGB	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HGB	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hemoglobin	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hemoglobin	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
14.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
14.1	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
15.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15.9	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
LYM	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
LYM	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Lymphocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Lymphocytes	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
2.6	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
2.6	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
1.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
1.1	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
3.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
3.2	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 1								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew		

Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
LYMLE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
LYMLE	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Lymphocytes/Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Lymphocytes/Leukocytes	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
28.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
28.3	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
15.8	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15.8	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
45.8	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
45.8	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
MONO	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
MONO	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Monocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Monocytes	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.4	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.4	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

Thou/uL	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.3	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.9	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
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- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
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- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
MONOLE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
MONOLE	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Monocytes/Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Monocytes/Leukocytes	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.5	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

%	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.9	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12.8	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12.8	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
L	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
N	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
N	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEUT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEUT	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Neutrophils	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Neutrophils	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.9	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.6	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.6	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.7	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.7	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEUTLE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEUTLE	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Neutrophils/Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Neutrophils/Leukocytes	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
65.6	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
65.6	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
38.4	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
38.4	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
74.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
74.2	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PLAT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PLAT	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Platelets	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Platelets	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
299	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
299	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
155	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
155	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
361	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
361	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							13
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
RBC	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
RBC	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Erythrocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Erythrocytes	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.86	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.86	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							14
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Mil/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Mil/uL	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.95	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.95	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.21	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.21	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							14

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
WBC	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
WBC	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Leukocytes	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
9.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
9.0	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Units							15

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.7	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.7	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
11.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
11.5	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:31 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Urinalysis

Accession Number 18389784U
 Date of Collection 17/JUL/2018
 DD/MON/YYYY(EN)
 Time of Collection 12:22
 HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Ketones	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Leukocyte Esterase	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Nitrite	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Occult Blood	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
pH	7.5		5.0	8.0		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Specific Gravity	1.004		1.005	1.030	L	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urine Bilirubin	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urine Glucose	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urine Protein	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urobilinogen	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:42 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UA	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UA	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	

Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18389784U	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18389784U	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17/JUL/2018	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17/JUL/2018	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	

Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12:22	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12:22	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	

Did the Subject fast 8 hours prior to collection?							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
KETONES	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
KETONES	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Ketones	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Ketones	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 4								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
LEUKASE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
LEUKASE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Leukocyte Esterase	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Leukocyte Esterase	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew		
Units								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
NEG, TRACE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	

NEG, TRACE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NITRITE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NITRITE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Nitrite	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Nitrite	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
OCCBLD	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
OCCBLD	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Occult Blood	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Occult Blood	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PH	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PH	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
pH	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
pH	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.5	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.0	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
8.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
8.0	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
SPGRAV	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
SPGRAV	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Specific Gravity	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Specific Gravity	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.004	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.004	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.005	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.005	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.030	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.030	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
L	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
N	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
N	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UBILI	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UBILI	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Bilirubin	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Bilirubin	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Units							7

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
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- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UGLUC	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UGLUC	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Glucose	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Glucose	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UPROT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UPROT	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Protein	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Protein	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UROBIL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UROBIL	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urobilinogen	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urobilinogen	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 1							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:13 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Virology

Accession Number 18390171S
Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)
Time of Collection 13:02
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Hep B Virus Surface Antigen	NON-REACTIVE		NON-REACTIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Hepatitis C Virus Antibody	NON-REACTIVE		NON-REACTIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
HIV Antibody	NON-REACTIVE		NON-REACTIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:42 PM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:25:49 PM CT	(b)(6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:48:52 PM CT	(b)(6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b)(6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b)(6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
VIROL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
VIROL	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18390171S	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18390171S	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17/JUL/2018	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17/JUL/2018	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
13:02	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
13:02	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HBSAG	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HBSAG	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hep B Virus Surface Antigen	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hep B Virus Surface Antigen	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NON-REACTIVE	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NON-REACTIVE	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HCAB	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HCAB	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hepatitis C Virus Antibody	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hepatitis C Virus Antibody	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NON-REACTIVE	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NON-REACTIVE	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HIVAB	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HIVAB	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HIV Antibody	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HIV Antibody	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NON-REACTIVE	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NON-REACTIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

NON-REACTIVE	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:48:52 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: Screening
Visit Date: 17/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Urine Drug Screen

Accession Number 18389784U
Date of Collection 17/JUL/2018
DD/MON/YYYY(EN)
Time of Collection 12:22
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Cotinine	DETECTED		DETECTED			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:42 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:25:34 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Category							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

UDS	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UDS	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18389784U	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18389784U	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17/JUL/2018	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17/JUL/2018	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12:22	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12:22	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:34 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
COTININE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
COTININE	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Cotinine	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Cotinine	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
DETECTED	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
DETECTED	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:34 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
DETECTED	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
DETECTED	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:34 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:34 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:34 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:34 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:34 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:34 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:25:34 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:19 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	Start of Week -1
Visit Date	26/JUL/2018 DD/MON/YYYY (EN)
Visit Number	2
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:29:04 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:58:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 11:14:05 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Start of Week - 1	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Start of Week - 1	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:29:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:14:05 AM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/19/2018 1:58:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:14:05 AM CT	(b) (6)	CRA	001-Mathew	

Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	

Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	

Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	

Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:40:35 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Start of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Vital Signs					
Not Done		<input type="checkbox"/>			
Date of Measurements		26/JUL/2018		DD/MON/YYYY(EN)	
Time of Measurements (24 Hour Clock)		07:53		HH:MM	
Not Done	Result	Test Name	Unit	Clinical Significance	
<input type="checkbox"/>	62.4	Weight	kg	NCS	CS
<input type="checkbox"/>	98.2	Temperature	F	NCS	CS
<input type="checkbox"/>	65	Heart Rate	beats/min	NCS	CS
<input type="checkbox"/>	14	Respiratory Rate	breaths/min	NCS	CS
<input type="checkbox"/>	103	Systolic Blood Pressure	mmHg	NCS	CS
<input type="checkbox"/>	69	Diastolic Blood Pressure	mmHg	NCS	CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Monitored	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	

Time of Measurements (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:53	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
07:53	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	

Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	

Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
62.4	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
62.4	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	

Unit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.2	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.2	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
65	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
65	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
103	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
103	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
69	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
69	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

mmHg	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:15:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:49:54 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Start of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Urine Cotinine Screen

Was the Urine Cotinine sample collected? ☒ No ☒ Yes
 Date of Collection 26/JUL/2018
 DD/MON/YYYY
 (EN)
 Is result positive for urine cotinine (greater than or equal to 500 ng/mL)? ☒ No ☒ Yes

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 9:35:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:46:30 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the Urine Cotinine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 9:35:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:46:30 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:35:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

26/JUL/2018	True	- Empty -	10/16/2018 12:46:30 PM CT	(b) (6)	CRA	001-Mathew	
Is result positive for urine cotinine (greater than or equal to 500 ng/mL)?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 9:35:17 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:46:30 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Start of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Pregnancy Test	
Was the pregnancy test performed?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
Date of Collection	26/JUL/2018 DD/MON/YYYY(EN)
Test Type	Serum
Pregnancy Test Result	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/9/2018 1:18:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/9/2018 1:18:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	10/16/2018 12:33:30 PM CT	(b) (6)	CRA	001-Mathew
Complete	11/6/2018 8:13:17 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	12/4/2018 7:47:35 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/19/2018 1:59:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	1/10/2019 3:30:29 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/11/2019 3:34:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/11/2019 3:42:56 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Was the pregnancy test performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	10/9/2018 1:18:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:33:30 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not performed							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/9/2018 1:18:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:33:30 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	10/9/2018 1:18:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	10/16/2018 12:33:30 PM CT	(b) (6)	CRA	001-Mathew	
Test Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	TEST TAKEN AS SERUM	10/9/2018 1:18:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	Please note that this was a serum test.	10/16/2018 12:33:30 PM CT	(b) (6)	CRA	001-Mathew	
URINE	False	NOTE WAS ADDED	11/6/2018 8:13:17 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	This will be updated in the next upgrade of the CRF.	12/4/2018 7:47:35 PM CT	(b) (6)	CRA	001-Mathew	
URINE	False	- Empty -	12/19/2018 1:59:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SERUM	False	Transcription Error	2/11/2019 3:34:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SERUM	True	- Empty -	2/11/2019 3:42:56 PM CT	(b) (6)	CRA	001-Mathew	
Pregnancy Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	10/9/2018 1:18:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:30 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Start of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Exhaled CO Measurement

Were exhaled CO measurements performed? ☒ No ☒ Yes

Date of Collection

26/JUL/2018
DD/MON/YYYY(EN)

Exhaled CO measurement (ppm)

16

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 9:36:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:56:57 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Were exhaled CO measurements performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 9:36:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:56:57 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:36:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	10/16/2018 12:56:57 PM CT	(b) (6)	CRA	001-Mathew	
Exhaled CO measurement (ppm)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16	False	- Empty -	8/24/2018 9:36:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16	True	- Empty -	10/16/2018 12:56:57 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** Start of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 26/JUL/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected? <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
Date of Collection	26/JUL/2018 DD/MON/YYYY(EN)
Test Name	Result
Opiates	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Amphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cocaine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cannabinoids	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Alcohol	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Methamphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/7/2018 10:15:28 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:15:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the Urine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
26/JUL/2018	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	

Result							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	

Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	

Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	

Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NEGATIVE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 9:33:54 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 9:36:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	Question value " updated to 'ALCOHOL' by VTS based on DataChange editId 2349.	10/7/2018 10:15:28 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPHETAMINE	False	Question value " updated to 'METHAMPHETAMINE' by VTS based on DataChange, StateChange editId 2309.	10/7/2018 10:15:28 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPHETAMINE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NEGATIVE	False	- Empty -	10/8/2018 6:15:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPH	False	Question value " updated to 'METHAMPH' by VTS based on DataChange editId 2349.	10/7/2018 10:15:28 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPH	True	- Empty -	10/16/2018 12:33:03 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: Start of Week -1
Visit Date: 26/JUL/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Urine Drug Screen

Accession Number 18394085U
Date of Collection 26/JUL/2018
DD/MON/YYYY(EN)
Time of Collection 08:46
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Cotinine	DETECTED	+	DETECTED	+	+	<input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Recheck	+	+	+	+

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:42 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:26:04 PM CT	(b) (6)	Setup Administrator	001-Mathew
No Data	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Incomplete	2/11/2019 12:43:08 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	2/11/2019 12:50:35 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Category	Field						1
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Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UDS	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
UDS	False	- Empty -	2/11/2019 12:43:09 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
UDS	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18394085U	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
18394085U	False	- Empty -	2/11/2019 12:43:09 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
18394085U	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
26/JUL/2018	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
26/JUL/2018	False	- Empty -	2/11/2019 12:43:09 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
26/JUL/2018	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
08:46	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
08:46	False	- Empty -	2/11/2019 12:43:09 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
08:46	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	False	- Empty -	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:50:35 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
COTININE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
COTININE	False	- Empty -	2/11/2019 12:43:09 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
COTININE	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Cotinine	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
Cotinine	False	- Empty -	2/11/2019 12:43:09 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
Cotinine	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
DETECTED	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
DETECTED	False	- Empty -	2/11/2019 12:43:09 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
DETECTED	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:50:35 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
DETECTED	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
- Empty -	False	Form cleared - Import error.	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
DETECTED	False	- Empty -	2/11/2019 12:43:09 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-02-11.txt
DETECTED	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:50:35 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:50:35 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:50:35 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:50:35 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:50:35 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:50:35 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	2/6/2019 9:21:32 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 12:50:35 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 2:00:09 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	End of Week -1
Visit Date	01/AUG/2018 DD/MON/YYYY (EN)
Visit Number	3
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:29:14 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:59:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 11:14:09 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Week - 1	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Week - 1	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:29:14 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:14:09 AM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/19/2018 1:59:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:14:09 AM CT	(b) (6)	CRA	001-Mathew	

Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	

Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	

Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	

Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Randomization	
Randomization Date	01/AUG/2018 DD/MON/YYYY(EN)
Assigned Product	Non-menthol VLN

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew
Complete	11/5/2018 7:01:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/3/2018 3:50:28 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/21/2018 1:14:45 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/21/2018 1:14:55 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:28:51 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Randomization Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001-Mathew	
02/AUG/2018	False	- Empty -	11/5/2018 7:01:45 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/AUG/2018	True	- Empty -	12/3/2018 3:50:28 PM CT	(b) (6)	CRA	001-Mathew	
01/AUG/2018	False	Transcription Error	12/21/2018 1:14:55 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	1/10/2019 3:28:51 PM CT	(b) (6)	CRA	001-Mathew	
Assigned Product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	10/16/2018 12:40:55 PM CT	(b) (6)	CRA	001- Mathew	
NON- MENTHOL VLN	False	Question value " updated to 'NON- MENTHOL VLN' by VTS based on DataChange editId 4125.	12/21/2018 1:14:45 PM CT	(b) (6)	Setup Administrator	001- Mathew	
NON- MENTHOL VLN	True	- Empty -	1/10/2019 3:28:51 PM CT	(b) (6)	CRA	001- Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Week -1
Visit Date: 01/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

24-Hour Urine Collection

Planned Timepoint	Was the sample collected?	If No, reason not collected	Collection Start Date	Collection Start Time (24 Hour Clock)	Collection Stop Date	Collection End Time (24 Hour Clock)	Total Weight (g)	Was any void in this 24 hour period lost or discarded?	Comment for lost or discarded sample
EOW -1	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes		31/JUL/2018 DD/MON/YYYY (EN)	19:12 HH:MM	01/AUG/2018 DD/MON/YYYY (EN)	19:13 HH:MM	2894	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 10:27:45 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Planned Timepoint							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EOW -1	False	- Empty -	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EOW -1	True	- Empty -	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew	
Was the sample collected?							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	monitored?						
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not collected							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew	
Collection Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	False	(This item is invalid.) CORRECT AS IS	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	Correct as entered.	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew	
Collection Start Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:12	False	(Collection Start Time should be 07:00 (+/- 30 minutes).) CORRECT AS IS	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:12	True	- Empty -	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew	
Collection Stop Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew	
Collection End Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:13	False	(Collection Start Time should be 07:00 (+/- 30 minutes).) CORRECT AS IS	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:13	True	Correct as entered.	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew	
Total Weight (g)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2894	False	- Empty -	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2894	True	- Empty -	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew	
Was any void in this 24 hour period lost or discarded?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew	
Comment for lost or discarded sample							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:56:23 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:54:44 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		<div>31/JUL/2018</div> <div>DD/MON/YYYY(EN)</div>		
Time of Measurements (24 Hour Clock)		<div>16:54</div> <div>HH:MM</div>		
Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>	98.3	Temperature	F	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	76	Heart Rate	beats/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	18	Respiratory Rate	breaths/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	97	Systolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	64	Diastolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Monitored	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	False	(Date of Measurements should be equal to the visit date.) correct as is	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	Correct as entered.	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	

Time of Measurements (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:54	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:54	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

cm	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

BMI	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.3	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.3	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
76	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
76	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	

Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	

Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	

Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
97	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
97	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
64	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
64	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:01 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:31 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Puffing Topography

Not Done ☐

Date of Collection 01/AUG/2018
DD/MON/YYYY(EN)

Was topography data collected? ☐ No ☐ Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/19/2018 9:36:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	11/5/2018 7:01:34 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	11/7/2018 7:44:14 PM CT	(b) (6)	CRA	001-Mathew
Complete	11/13/2018 5:28:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/21/2018 3:08:36 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Group: PF							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Per the source, the date should be 01-Aug-2018. Please verify.	11/7/2018 7:44:14 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	UPDATED	11/13/2018 5:28:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Corrected.	11/21/2018 3:08:36 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Date of Collection							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	10/19/2018 9:36:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/AUG/2018	False	Transcription Error	11/5/2018 7:01:34 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/AUG/2018	True	- Empty -	11/7/2018 7:44:14 PM CT	(b) (6)	CRA	001-Mathew	
01/AUG/2018	False	Transcription Error	11/13/2018 5:28:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	11/21/2018 3:08:36 PM CT	(b) (6)	CRA	001-Mathew	
Was topography data collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	10/19/2018 9:36:57 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	11/7/2018 7:44:14 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Week -1
Visit Date: 01/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Product Return

Product Name Non-menthol UB
If Usual Brand, Specify MARLBORO
Date Returned 31/JUL/2018
DD/MON/YYYY(EN)
Cigarette butts returned 105
Did the subject consume any tobacco products other than the cigarettes reported in the e-Diary? ☒ No ☐ Yes
Is there any additional information to provide about the difference between reported cigarette use and number of cigarettes and butts returned? ☒ No ☐ Yes
Specify additional information 12 BUTTS NOT ACCOUNTED FOR

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Product Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL UB	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL UB	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	
If Usual Brand, Specify							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MARLBORO	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MARLBORO	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	

Date Returned 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	

Number of cigarettes returned 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
0	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
0	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	

Cigarette butts returned 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
105	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
105	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	

Number of Non-VLN butts returned 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	

Did the subject consume any tobacco products other than the cigarettes reported in the e-Diary? 1

Response	Field Moni	Notes	Date/Time	User	Role	Site	Source
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	tored?						
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	
If yes, please indicate when							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	
If yes, estimate amount							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	
Is there any additional information to provide about the difference between reported cigarette use and number of cigarettes and butts returned?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	
Specify additional information							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12 BUTTS NOT ACCOUNTED FOR	False	- Empty -	8/29/2018 1:48:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12 BUTTS NOT ACCOUNTED FOR	True	- Empty -	12/6/2018 8:14:05 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Product Dispensed	
Product Name	Non-menthol VLN
If Usual Brand, Specify	
Date Dispensed	01/AUG/2018 DD/MON/YYYY(EN)
Number of cigarettes dispensed	420

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/26/2018 1:56:46 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/26/2018 12:20:29 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Product Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	False	- Empty -	8/26/2018 1:56:46 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	True	- Empty -	11/26/2018 12:20:29 PM CT	(b) (6)	CRA	001-Mathew	
If Usual Brand, Specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:56:46 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	11/26/2018 12:20:29 PM CT	(b) (6)	CRA	001-Mathew	

Date Dispensed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 1:56:46 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	11/26/2018 12:20:29 PM CT	(b) (6)	CRA	001-Mathew	
Number of cigarettes dispensed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
420	False	- Empty -	8/26/2018 1:56:46 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
420	True	- Empty -	11/26/2018 12:20:29 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Pregnancy Test

Was the pregnancy test performed? ☒ No ☒ Yes
Date of Collection B 31/JUL/2018 DD/MON/YYYY(EN)
Test Type Urine
Pregnancy Test Result ☒ Negative ☒ Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/9/2018 1:19:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	10/16/2018 12:34:22 PM CT	(b) (6)	CRA	001-Mathew
Complete	11/6/2018 8:15:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	12/4/2018 7:46:22 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/19/2018 1:59:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:30:33 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the pregnancy test performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	10/9/2018 1:19:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:34:22 PM CT	(b) (6)	CRA	001-Mathew	

If No, reason not performed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/9/2018 1:19:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:34:22 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	False	(Date should be equal to the visit date.) CORRECT AS IS	10/9/2018 1:19:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	Correct as entered.	10/16/2018 12:34:22 PM CT	(b) (6)	CRA	001-Mathew	
Test Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	- Empty -	10/9/2018 1:19:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	Please note this was a serum test.	10/16/2018 12:34:22 PM CT	(b) (6)	CRA	001-Mathew	
URINE	False	NOTE ADDED	11/6/2018 8:15:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	TEST TAKEN AS SERUM	11/6/2018 8:15:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	False	This will be updated in the next upgrade of the CRF.	12/4/2018 7:46:22 PM CT	(b) (6)	CRA	001-Mathew	
URINE	False	- Empty -	12/19/2018 1:59:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	True	- Empty -	1/10/2019 3:30:33 PM CT	(b) (6)	CRA	001-Mathew	
Pregnancy Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/9/2018 1:16:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	10/9/2018 1:19:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:34:22 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Plasma/Blood Sampling				
Not Done	If Not Done, specify	Assay	Collection Date	Collection Time
<input type="checkbox"/>		Cotinine	01/AUG/2018 DD/MON/YYYY(EN)	13:29 HH:MM
<input type="checkbox"/>		COHb	01/AUG/2018 DD/MON/YYYY(EN)	13:29 HH:MM
<input type="checkbox"/>		Nicotine	02/AUG/2018 DD/MON/YYYY(EN)	08:05 HH:MM

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/11/2019 1:53:42 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/12/2019 4:30:20 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Not Done							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	2/11/2019 1:53:42 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
If Not Done, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
Assay							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COTININE	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COTININE	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
Collection Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:29	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:29	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							2
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
If Not Done, specify							2
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
Assay							2
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COHB	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COHB	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
Collection Date							2
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							2

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:29	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:29	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
If Not Done, specify							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
Assay							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NICOTINE	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NICOTINE	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
Collection Date							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
01/AUG/2018	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	

02/AUG/2018	False	Transcription Error	2/11/2019 1:53:42 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/AUG/2018	True	- Empty -	2/12/2019 4:30:20 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:30	False	- Empty -	8/26/2018 1:57:26 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:30	True	- Empty -	10/16/2018 12:47:49 PM CT	(b) (6)	CRA	001-Mathew	
08:05	False	Transcription Error	2/11/2019 1:53:42 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08:05	True	- Empty -	2/12/2019 4:30:20 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week -1 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 01/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
Date of Collection	31/JUL/2018 DD/MON/YYYY(EN)
Test Name	Result
Opiates	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive
Amphetamine	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive
Cocaine	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive
Cannabinoids	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive
Alcohol	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive
Methamphetamine	<input checked="" type="radio"/> Negative <input checked="" type="radio"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/7/2018 10:27:25 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:17:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the Urine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	False	(Date of Drug Screen should be equal to the visit date.) correct as is	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
31/JUL/2018	True	Correct as entered.	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	

Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

AMPHET	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NEGATIVE	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/26/2018 1:54:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/27/2018 9:58:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	Question value " updated to 'ALCOHOL' by VTS based on DataChange editId 2344.	10/7/2018 10:27:25 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPHETAMINE	False	Question value " updated to 'METHAMPHETAMINE' by VTS based on DataChange, StateChange editId 2304.	10/7/2018 10:27:25 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPHETAMINE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NEGATIVE	False	- Empty -	10/8/2018 6:17:30 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPH	False	Question value " updated to 'METHAMPH' by VTS based on DataChange editId 2344.	10/7/2018 10:27:25 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPH	True	- Empty -	10/16/2018 12:33:51 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	End of Week 2
Visit Date	15/AUG/2018 DD/MON/YYYY (EN)
Visit Number	4
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:29:29 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:59:15 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 11:14:15 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Week 2	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Week 2	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:29:29 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:14:15 AM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/19/2018 1:59:15 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:14:15 AM CT	(b) (6)	CRA	001-Mathew	

Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	

Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	

Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	

Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:41:19 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Week 2
Visit Date: 15/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

24-Hour Urine Collection

Planned Timepoint	Was the sample collected?	If No, reason not collected	Collection Start Date	Collection Start Time (24 Hour Clock)	Collection Stop Date	Collection End Time (24 Hour Clock)	Total Weight (g)	Was any void in this 24 hour period lost or discarded?	Comment for lost or discarded sample
EOW 2	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes		15/AUG/2018 DD/MON/YYYY (EN)	<input checked="" type="checkbox"/> 19:08 HH:MM	16/AUG/2018 DD/MON/YYYY (EN)	<input checked="" type="checkbox"/> 19:18 HH:MM	3795.5	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 10:43:48 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Planned Timepoint							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EOW 2	False	- Empty -	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EOW 2	True	- Empty -	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew	
Was the sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not collected							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew	
Collection Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	- Empty -	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	- Empty -	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew	
Collection Start Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:08	False	(Collection Start Time should be 07:00 (+/- 30 minutes).) CORRECT AS IS	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:08	True	- Empty -	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew	
Collection Stop Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	False	- Empty -	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	True	- Empty -	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew	
Collection End Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:18	False	(Collection Start Time should be 07:00 (+/- 30 minutes).) CORRECT AS IS	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:18	True	Correct as entered.	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew	
Total Weight (g)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	tored?						
3795.5	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3795.5	False	- Empty -	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3795.5	True	- Empty -	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew	
Was any void in this 24 hour period lost or discarded?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew	
Comment for lost or discarded sample							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:55:29 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 2 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 15/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		15/AUG/2018 DD/MON/YYYY(EN)		
Time of Measurements (24 Hour Clock)		16:36 HH:MM		
Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>	98.2	Temperature	F	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	70	Heart Rate	beats/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	12	Respiratory Rate	breaths/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	99	Systolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	63	Diastolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Monitored	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Time of Measurements (24 Hour Clock)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:36	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:36	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	

Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.2	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.2	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
70	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
70	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	

Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
99	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
99	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
63	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
63	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:03:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:50:57 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 2 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 15/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Puffing Topography

Not Done ☐

Date of Collection 16/AUG/2018
DD/MON/YYYY(EN)

Was topography data collected? ☒ No ☒ Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/19/2018 9:37:12 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	11/5/2018 7:02:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/7/2018 7:59:47 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	- Empty -	10/19/2018 9:37:12 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	False	Transcription Error	11/5/2018 7:02:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	True	- Empty -	11/7/2018 7:59:47 PM CT	(b) (6)	CRA	001-Mathew	
Was topography data collected?							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	10/19/2018 9:37:12 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	11/7/2018 7:59:47 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 2 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 15/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Product Dispensed	
Product Name	Non-menthol VLN
If Usual Brand, Specify	
Date Dispensed	13/AUG/2018 DD/MON/YYYY(EN)
Number of cigarettes dispensed	380

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/17/2018 12:01:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/26/2018 12:27:58 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Product Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	False	- Empty -	9/17/2018 12:01:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	True	- Empty -	11/26/2018 12:27:58 PM CT	(b) (6)	CRA	001-Mathew	
If Usual Brand, Specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:01:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	11/26/2018 12:27:58 PM CT	(b) (6)	CRA	001-Mathew	
Date Dispensed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13/AUG/2018	False	- Empty -	9/17/2018 12:01:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13/AUG/2018	True	- Empty -	11/26/2018 12:27:58 PM CT	(b) (6)	CRA	001-Mathew	
Number of cigarettes dispensed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
380	False	- Empty -	9/17/2018 12:01:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
380	True	- Empty -	11/26/2018 12:27:58 PM CT	(b) (6)	CRA	001-Mathew	
380	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Week 2
Visit Date: 15/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Product Return

Product Name	Non-menthol VLN
If Usual Brand, Specify	
Date Returned	15/AUG/2018 DD/MON/YYYY(EN)
Number of cigarettes returned	148
Cigarette butts returned	271
Number of Non-VLN butts returned	21
Did the subject consume any tobacco products other than the cigarettes reported in the e-Diary?	<input type="radio"/> No <input type="radio"/> Yes
Is there any additional information to provide about the difference between reported cigarette use and number of cigarettes and butts returned?	<input type="radio"/> No <input type="radio"/> Yes
Specify additional information	1 TOTAL. 38 BUTTS NOT RETURNED. 39 CIGARETTES NOT ACCOUNTED FOR. 14 NON VLN BUTTS NOT ACCOUNTED FOR. THREW SOME OUT WINDOW

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/11/2018 2:47:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/7/2018 7:48:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/7/2018 1:05:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:32:47 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Product Name	1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	False	- Empty -	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	True	- Empty -	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	

If Usual Brand, Specify 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/11/2018 2:47:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	

Date Returned 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	- Empty -	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	- Empty -	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	

Number of cigarettes returned 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
148	False	- Empty -	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
148	True	- Empty -	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	

Cigarette butts returned 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
271	False	- Empty -	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
271	True	- Empty -	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	

Number of Non-VLN butts returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
21	False	- Empty -	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
21	True	- Empty -	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	

Did the subject consume any tobacco products other than the cigarettes reported in the e-Diary?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Please change to no as the subject returned less nonVLN butts than were reported.	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	
N	False	updated	12/7/2018 7:48:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Transcription Error	12/7/2018 7:48:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	Corrected.	1/10/2019 3:32:47 PM CT	(b) (6)	CRA	001-Mathew	

If yes, please indicate when							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
A FEW TIMES	False	- Empty -	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
A FEW TIMES	True	- Empty -	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/7/2018 7:48:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:32:47 PM CT	(b) (6)	CRA	001-Mathew	

If yes, estimate amount							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
35	False	- Empty -	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
35	True	- Empty -	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	

- Empty -	False	- Empty -	12/7/2018 7:48:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:32:47 PM CT	(b) (6)	CRA	001-Mathew	
Is there any additional information to provide about the difference between reported cigarette use and number of cigarettes and butts returned?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	10/11/2018 2:47:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	
Specify additional information							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/26/2018 2:56:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1 TOTAL. 48 BUTTS NOT RETURNED. 49 CIGARETTES NOT ACCOUNTED FOR. 14 NON VLN BUTTS NOT ACCOUNTED FOR. THREW SOME OUT WINDOW	False	- Empty -	10/11/2018 2:47:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1 TOTAL. 48 BUTTS NOT RETURNED. 49 CIGARETTES NOT ACCOUNTED FOR. 14 NON VLN BUTTS NOT ACCOUNTED FOR. THREW SOME OUT WINDOW	False	The total amount of VLN reported was listed as 233 in the Clinical Ink diary. Please update the UB reconciliation form and this section of this form.	12/6/2018 9:15:12 PM CT	(b) (6)	CRA	001-Mathew	
1 TOTAL. 38 BUTTS NOT RETURNED. 39 CIGARETTES NOT ACCOUNTED FOR. 14 NON VLN BUTTS NOT ACCOUNTED FOR. THREW SOME OUT WINDOW	False	Transcription Error	12/7/2018 1:05:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1 TOTAL. 38 BUTTS NOT RETURNED. 39 CIGARETTES NOT ACCOUNTED FOR. 14 NON VLN BUTTS NOT ACCOUNTED FOR. THREW SOME OUT WINDOW	False	updated	12/7/2018 1:05:11 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1 TOTAL. 38 BUTTS NOT RETURNED. 39							

CIGARETTES NOT ACCOUNTED FOR. 14 NON VLN BUTTS NOT ACCOUNTED FOR. THREW SOME OUT WINDOW	True	Corrected.	1/10/2019 3:32:47 PM CT	(b) (6)	CRA	001- Mathew
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iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 2 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 15/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Plasma/Blood Sampling				
Not Done <input type="checkbox"/>				
Not Done	If Not Done, specify	Assay	Collection Date	Collection Time
<input type="checkbox"/>		Cotinine	16/AUG/2018 DD/MON/YYYY(EN)	13:16 HH:MM
<input type="checkbox"/>		COHb	16/AUG/2018 DD/MON/YYYY(EN)	13:15 HH:MM
<input type="checkbox"/>		Nicotine	17/AUG/2018 DD/MON/YYYY(EN)	08:03 HH:MM

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/11/2019 1:54:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/12/2019 4:37:27 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 1:54:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 4:37:27 PM CT	(b) (6)	CRA	001-Mathew	

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	

If Not Done, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	

Assay							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COTININE	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COTININE	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	

Collection Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

16/AUG/2018	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:16	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:16	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
If Not Done, specify							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
Assay							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COHB	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COHB	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
Collection Date							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

16/AUG/2018	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:15	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:15	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
If Not Done, specify							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
Assay							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NICOTINE	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NICOTINE	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
Collection Date							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
17/AUG/2018	False	Transcription Error	2/11/2019 1:54:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/AUG/2018	True	- Empty -	2/12/2019 4:37:27 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:16	False	- Empty -	9/5/2018 7:05:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:16	True	- Empty -	10/16/2018 12:48:09 PM CT	(b) (6)	CRA	001-Mathew	
08:03	False	Transcription Error	2/11/2019 1:54:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08:03	True	- Empty -	2/12/2019 4:37:27 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 2 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 15/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Date of Collection	15/AUG/2018 DD/MON/YYYY(EN)
Test Name	Result
Opiates	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Amphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cocaine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cannabinoids	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Alcohol	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Methamphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/7/2018 10:43:33 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:14:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/5/2018 11:22:30 AM CT	(b) (6)	CRA	001-Mathew
Complete	12/19/2018 1:59:20 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 12:01:31 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Form: Urine Drug Screen

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please add the pregnancy test to the eCRF.	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	This will be updated during the next CRF upgrade.	12/5/2018 11:22:30 AM CT	(b) (6)	CRA	001-Mathew	

Was the Urine sample collected?

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NEGATIVE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

CANNABINOIDS	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:01:14 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:04:36 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	Question value " updated to 'ALCOHOL' by VTS based on DataChange editId 2345.	10/7/2018 10:43:33 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPHETAMINE	False	Question value " updated to 'METHAMPHETAMINE' by VTS based on DataChange, StateChange editId 2305.	10/7/2018 10:43:33 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPHETAMINE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NEGATIVE	False	- Empty -	10/8/2018 6:14:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPH	False	Question value " updated to 'METHAMPH' by VTS based on DataChange editId 2345.	10/7/2018 10:43:33 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPH	True	- Empty -	10/16/2018 12:36:11 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 2 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 15/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Pregnancy Test

Was the pregnancy test performed? ☒ No ☒ Yes
Date of Collection 15/AUG/2018
DD/MON/YYYY(EN)
Test Type Urine
Pregnancy Test Result ☒ Negative ☒ Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	12/18/2018 2:29:29 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/21/2018 8:05:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:30:48 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the pregnancy test performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:29 PM CT	(b) (6)	Setup Administrator	001-Mathew	
Y	False	- Empty -	12/21/2018 8:05:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	1/10/2019 3:30:48 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not performed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:29 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	12/21/2018 8:05:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:30:48 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:29 PM CT	(b) (6)	Setup Administrator	001-Mathew	
15/AUG/2018	False	- Empty -	12/21/2018 8:05:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/AUG/2018	True	- Empty -	1/10/2019 3:30:48 PM CT	(b) (6)	CRA	001-Mathew	

Test Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:29 PM CT	(b) (6)	Setup Administrator	001-Mathew	
URINE	False	- Empty -	12/21/2018 8:05:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	True	- Empty -	1/10/2019 3:30:48 PM CT	(b) (6)	CRA	001-Mathew	

Pregnancy Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:29 PM CT	(b) (6)	Setup Administrator	001-Mathew	
NEGATIVE	False	- Empty -	12/21/2018 8:05:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	1/10/2019 3:30:48 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	End of Week 4
Visit Date	29/AUG/2018 DD/MON/YYYY (EN)
Visit Number	5
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew
Complete	10/19/2018 9:37:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	11/7/2018 7:19:59 PM CT	(b) (6)	CRA	001-Mathew
Monitored	11/7/2018 7:20:08 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:29:39 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:59:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 11:14:23 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	

Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	

Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Week 4	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Week 4	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	

Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29/AUG/2018	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29/AUG/2018	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	

Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	

Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	10/19/2018 9:37:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	11/7/2018 7:20:08 PM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	True	- Empty -	11/7/2018 7:20:08 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:29:39 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:14:23 AM CT	(b) (6)	CRA	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Should this be yes due to AE #2?	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	
Y	False	UPDATED	10/19/2018 9:37:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Transcription Error	10/19/2018 9:37:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Updated.	11/7/2018 7:19:59 PM CT	(b) (6)	CRA	001-Mathew	
Y	True	- Empty -	11/7/2018 7:20:08 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:42:05 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 4 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 29/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		29/AUG/2018 DD/MON/YYYY(EN)		
Time of Measurements (24 Hour Clock)		08:31 HH:MM		
Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>	98.1	Temperature	F	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	66	Heart Rate	beats/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	14	Respiratory Rate	breaths/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	96	Systolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	64	Diastolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Monitored	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29/AUG/2018	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29/AUG/2018	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Time of Measurements (24 Hour Clock)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08:31	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08:31	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	

Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.1	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.1	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
66	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
66	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	

Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
96	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
96	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
64	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
64	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:38 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:25 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 4 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 29/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Product Dispensed	
Product Name	Non-menthol VLN
If Usual Brand, Specify	
Date Dispensed	28/AUG/2018 DD/MON/YYYY(EN)
Number of cigarettes dispensed	440

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/18/2018 12:54:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/26/2018 12:33:42 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Product Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	False	- Empty -	9/18/2018 12:54:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	True	- Empty -	11/26/2018 12:33:42 PM CT	(b) (6)	CRA	001-Mathew	
If Usual Brand, Specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 12:54:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	11/26/2018 12:33:42 PM CT	(b) (6)	CRA	001-Mathew	
Date Dispensed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
28/AUG/2018	False	- Empty -	9/18/2018 12:54:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
28/AUG/2018	True	- Empty -	11/26/2018 12:33:42 PM CT	(b) (6)	CRA	001-Mathew	
Number of cigarettes dispensed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
440	False	- Empty -	9/18/2018 12:54:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
440	True	- Empty -	11/26/2018 12:33:42 PM CT	(b) (6)	CRA	001-Mathew	
440	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Week 4
Visit Date: 29/AUG/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Product Return

Product Name	Non-menthol VLN
If Usual Brand, Specify	
Date Returned	29/AUG/2018 DD/MON/YYYY(EN)
Number of cigarettes returned	151
Cigarette butts returned	216
Number of Non-VLN butts returned	0
Did the subject consume any tobacco products other than the cigarettes reported in the e-Diary?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Is there any additional information to provide about the difference between reported cigarette use and number of cigarettes and butts returned?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Specify additional information	13 TOTAL. 7 BUTTS NOT RETURNED. 6 CIGARETTES NOT ACCOUNTED FOR. 2 NON VLN BUTTS NOT ACCOUNTED FOR

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/11/2018 2:51:17 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/7/2018 1:14:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:33:25 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Product Name							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	False	- Empty -	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	True	- Empty -	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	
If Usual Brand, Specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/11/2018 2:51:17 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	
Date Returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29/AUG/2018	False	- Empty -	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29/AUG/2018	True	- Empty -	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	
Number of cigarettes returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
151	False	- Empty -	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
151	True	- Empty -	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	
Cigarette butts returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
216	False	- Empty -	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
216	True	- Empty -	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	
Number of Non-VLN butts returned							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
0	False	- Empty -	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
0	True	- Empty -	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	

Did the subject consume any tobacco products other than the cigarettes reported in the e-Diary?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	

If yes, please indicate when							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/11/2018 2:51:17 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	

If yes, estimate amount							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/11/2018 2:51:17 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	

Is there any additional information to provide about the difference between reported cigarette use and number of cigarettes and butts returned?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	10/11/2018 2:51:17 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

Y	True	- Empty -	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	
Specify additional information							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/26/2018 2:57:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13 TOTAL. 27 BUTTS NOT RETURNED. 40 CIGARETTES NOT ACCOUNTED FOR	False	- Empty -	10/11/2018 2:51:17 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13 TOTAL. 27 BUTTS NOT RETURNED. 40 CIGARETTES NOT ACCOUNTED FOR	False	The total amount of VLN reported was listed as 223 and 2 of the nonVLN reported in the Clinical Ink diary. Please update the UB reconciliation form and this section of this form.	12/6/2018 10:00:07 PM CT	(b) (6)	CRA	001-Mathew	
13 TOTAL. 7 BUTTS NOT RETURNED. 6 CIGARETTES NOT ACCOUNTED FOR. 2 NON VLN BUTTS NOT ACCOUNTED FOR	False	Transcription Error	12/7/2018 1:14:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13 TOTAL. 7 BUTTS NOT RETURNED. 6 CIGARETTES NOT ACCOUNTED FOR. 2 NON VLN BUTTS NOT ACCOUNTED FOR	False	updated	12/7/2018 1:14:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13 TOTAL. 7 BUTTS NOT RETURNED. 6 CIGARETTES NOT ACCOUNTED FOR. 2 NON VLN BUTTS NOT ACCOUNTED FOR	True	Corrected.	1/10/2019 3:33:25 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 4 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 29/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Date of Collection	29/AUG/2018 DD/MON/YYYY(EN)
Test Name	Result
Opiates	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Amphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cocaine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cannabinoids	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Alcohol	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Methamphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/7/2018 10:43:58 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:14:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/5/2018 11:22:38 AM CT	(b) (6)	CRA	001-Mathew
Complete	12/19/2018 1:59:31 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 12:01:35 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Form: Urine Drug Screen

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please add the pregnancy test to the eCRF.	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	This will be updated during the next CRF upgrade.	12/5/2018 11:22:38 AM CT	(b) (6)	CRA	001-Mathew	

Was the Urine sample collected?

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29/AUG/2018	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29/AUG/2018	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NEGATIVE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

CANNABINOIDS	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/5/2018 7:05:42 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/5/2018 7:06:53 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	Question value " updated to 'ALCOHOL' by VTS based on DataChange editId 2346.	10/7/2018 10:43:58 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPHETAMINE	False	Question value " updated to 'METHAMPHETAMINE' by VTS based on DataChange, StateChange editId 2306.	10/7/2018 10:43:58 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPHETAMINE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NEGATIVE	False	- Empty -	10/8/2018 6:14:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPH	False	Question value " updated to 'METHAMPH' by VTS based on DataChange editId 2346.	10/7/2018 10:43:58 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPH	True	- Empty -	10/16/2018 12:36:36 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 4 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 29/AUG/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Pregnancy Test

Was the pregnancy test performed? ☒ No ☒ Yes
Date of Collection 29/AUG/2018
DD/MON/YYYY(EN)
Test Type Urine
Pregnancy Test Result ☒ Negative ☒ Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	12/18/2018 2:29:39 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/21/2018 8:05:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:31:00 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Was the pregnancy test performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:39 PM CT	(b) (6)	Setup Administrator	001-Mathew	
Y	False	- Empty -	12/21/2018 8:05:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	1/10/2019 3:31:00 PM CT	(b) (6)	CRA	001-Mathew	

If No, reason not performed

							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:39 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	12/21/2018 8:05:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:31:00 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:39 PM CT	(b) (6)	Setup Administrator	001-Mathew	
29/AUG/2018	False	- Empty -	12/21/2018 8:05:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
29/AUG/2018	True	- Empty -	1/10/2019 3:31:00 PM CT	(b) (6)	CRA	001-Mathew	

Test Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:39 PM CT	(b) (6)	Setup Administrator	001-Mathew	
URINE	False	- Empty -	12/21/2018 8:05:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	True	- Empty -	1/10/2019 3:31:00 PM CT	(b) (6)	CRA	001-Mathew	

Pregnancy Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:39 PM CT	(b) (6)	Setup Administrator	001-Mathew	
NEGATIVE	False	- Empty -	12/21/2018 8:05:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	1/10/2019 3:31:00 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	End of Week 6
Visit Date	12/SEP/2018 DD/MON/YYYY (EN)
Visit Number	6
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	12/18/2018 2:29:49 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 1:59:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 11:14:27 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Week 6	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Week 6	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
6	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
6	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/18/2018 2:29:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:14:27 AM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TOBACCO CESSATION INFORMATION NOT REQUIRED AT THIS TIMEPOINT	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	- Empty -	12/19/2018 1:59:35 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 11:14:27 AM CT	(b) (6)	CRA	001-Mathew	

Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	

Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	

Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	

Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:42:55 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Week 6
Visit Date: 12/SEP/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

24-Hour Urine Collection

Planned Timepoint	Was the sample collected?	If No, reason not collected	Collection Start Date	Collection Start Time (24 Hour Clock)	Collection Stop Date	Collection End Time (24 Hour Clock)	Total Weight (g)	Was any void in this 24 hour period lost or discarded?	Comment for lost or discarded sample
EOW 6	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes		12/SEP/2018 DD/MON/YYYY (EN)	B 19:08 HH:MM	13/SEP/2018 DD/MON/YYYY (EN)	B 19:10 HH:MM	3600	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 11:23:26 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Planned Timepoint							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EOW 6	False	- Empty -	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EOW 6	True	- Empty -	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew	
Was the sample collected?							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not collected							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew	
Collection Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	False	- Empty -	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	True	- Empty -	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew	
Collection Start Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:08	False	(Collection Start Time should be 07:00 (+/- 30 minutes).) correct as is	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:08	True	- Empty -	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew	
Collection Stop Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13/SEP/2018	False	- Empty -	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13/SEP/2018	True	- Empty -	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew	
Collection End Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:10	False	(Collection Start Time should be 07:00 (+/- 30 minutes).) correct as is	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19:10	True	Correct as entered.	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew	
Total Weight (g)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3600	False	- Empty -	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3600	True	- Empty -	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew	
Was any void in this 24 hour period lost or discarded?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew	
Comment for lost or discarded sample							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:12 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:16 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 6 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 12/SEP/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		12/SEP/2018 DD/MON/YYYY(EN)		
Time of Measurements (24 Hour Clock)		16:51 HH:MM		
Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>				<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	98.2	Temperature	F	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	70	Heart Rate	beats/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	16	Respiratory Rate	breaths/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	95	Systolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	65	Diastolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Monitored	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Time of Measurements (24 Hour Clock)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:51	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:51	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	

Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.2	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
98.2	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
70	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
70	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	

Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
95	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
95	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
65	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
65	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:01 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:51:47 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 6 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 12/SEP/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Puffing Topography	
Not Done	<input type="checkbox"/>
Date of Collection	13/SEP/2018 DD/MON/YYYY(EN)
Was topography data collected?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/19/2018 9:37:59 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	11/5/2018 7:02:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/7/2018 8:13:57 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	False	- Empty -	10/19/2018 9:37:59 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13/SEP/2018	False	Transcription Error	11/5/2018 7:02:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13/SEP/2018	True	- Empty -	11/7/2018 8:13:57 PM CT	(b) (6)	CRA	001-Mathew	
Was topography data collected?							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	10/19/2018 9:37:59 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	11/7/2018 8:13:57 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Week 6
Visit Date: 12/SEP/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Product Return

Product Name Non-menthol VLN

If Usual Brand, Specify

Date Returned 12/SEP/2018
DD/MON/YYYY(EN)

Number of cigarettes returned 152

Cigarette butts returned 274

Number of Non-VLN butts returned 10

Did the subject consume any tobacco products other than the cigarettes reported in the e-Diary?
☒ No ☒ Yes

If yes, please indicate when A Few Times

If yes, estimate amount 4

Is there any additional information to provide about the difference between reported cigarette use and number of cigarettes and butts returned?
☒ No ☒ Yes

Specify additional information 14 TOTAL. 63 BUTTS NOT RETURNED. 77 CIGARETTES NOT ACCOUNTED FOR. 4 NON VLN BUTTS NOT ACCOUNTED FOR. FORGOT 1/2 PACK UNUSED AT HOME AND MISSED 3 DIARY ENTRIES

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/11/2018 2:52:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/7/2018 7:32:52 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:33:44 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Product Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	False	- Empty -	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NON-MENTHOL VLN	True	- Empty -	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew	

If Usual Brand, Specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/11/2018 2:52:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew	

Date Returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	False	- Empty -	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	True	- Empty -	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew	

Number of cigarettes returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
152	False	- Empty -	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
152	True	- Empty -	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew	

Cigarette butts returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

274	False	- Empty -	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
274	True	- Empty -	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew	
Number of Non-VLN butts returned							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10	False	- Empty -	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10	True	- Empty -	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject consume any tobacco products other than the cigarettes reported in the e-Diary?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew	
If yes, please indicate when							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
A FEW TIMES	False	- Empty -	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
A FEW TIMES	True	- Empty -	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew	
If yes, estimate amount							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
6	False	- Empty -	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
6	False	Please change to 4 as the subject returned 10 nonVLN butts and reported 6 nonVLN.	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew	
4	False	updated	12/7/2018 7:32:52 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	False	Transcription Error	12/7/2018 7:32:52 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	True	Corrected.	1/10/2019 3:33:44 PM CT	(b) (6)	CRA	001-Mathew	

Is there any additional information to provide about the difference between reported cigarette use and number of cigarettes and butts returned?								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
Y	False	- Empty -	10/11/2018 2:52:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
Y	True	- Empty -	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew		
Specify additional information								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	9/26/2018 2:58:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
14 TOTAL. 63 BUTTS NOT RETURNED. 77 CIGARETTES NOT ACCOUNTED FOR. 4 NON VLN BUTTS NOT ACCOUNTED FOR. FORGOT 1/2 PACK UNUSED AT HOME AND MISSED 3 DIARY ENTRIES	False	- Empty -	10/11/2018 2:52:44 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
14 TOTAL. 63 BUTTS NOT RETURNED. 77 CIGARETTES NOT ACCOUNTED FOR. 4 NON VLN BUTTS NOT ACCOUNTED FOR. FORGOT 1/2 PACK UNUSED AT HOME AND MISSED 3 DIARY ENTRIES	True	- Empty -	12/6/2018 10:36:04 PM CT	(b) (6)	CRA	001-Mathew		

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 6 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 12/SEP/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Plasma/Blood Sampling				
Not Done <input type="checkbox"/>				
Not Done	If Not Done, specify	Assay	Collection Date	Collection Time
<input type="checkbox"/>		Cotinine	13/SEP/2018 DD/MON/YYYY(EN)	13:14 HH:MM
<input type="checkbox"/>		COHb	13/SEP/2018 DD/MON/YYYY(EN)	13:13 HH:MM
<input type="checkbox"/>		Nicotine	14/SEP/2018 DD/MON/YYYY(EN)	08:03 HH:MM

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/11/2019 1:54:40 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/13/2019 10:13:14 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 1:54:40 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 10:13:14 AM CT	(b) (6)	CRA	001-Mathew	

Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	

If Not Done, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	

Assay							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COTININE	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COTININE	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	

Collection Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13/SEP/2018	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

13/SEP/2018	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:14	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:14	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
If Not Done, specify							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
Assay							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COHB	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COHB	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
Collection Date							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

13/SEP/2018	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13/SEP/2018	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
Collection Time							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:13	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:13	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
If Not Done, specify							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
Assay							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NICOTINE	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NICOTINE	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
Collection Date							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13/SEP/2018	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13/SEP/2018	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
14/SEP/2018	False	Transcription Error	2/11/2019 1:54:40 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	True	- Empty -	2/13/2019 10:13:14 AM CT	(b) (6)	CRA	001-Mathew	
Collection Time							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:14	False	- Empty -	9/17/2018 12:59:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:14	True	- Empty -	10/16/2018 12:48:29 PM CT	(b) (6)	CRA	001-Mathew	
08:03	False	Transcription Error	2/11/2019 1:54:40 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
08:03	True	- Empty -	2/13/2019 10:13:14 AM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 6 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 12/SEP/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Date of Collection	12/SEP/2018 DD/MON/YYYY(EN)
Test Name	Result
Opiates	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Amphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cocaine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cannabinoids	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Alcohol	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Methamphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/7/2018 11:23:11 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:14:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/5/2018 11:22:49 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Form: Urine Drug Screen

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please add the pregnancy test to the eCRF.	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	This will be updated during the next CRF upgrade.	12/5/2018 11:22:49 AM CT	(b) (6)	CRA	001-Mathew	

Was the Urine sample collected?

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	

Test Name

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	

Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	

Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	

Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

CANNABINOIDS	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/17/2018 12:57:38 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	Question value " updated to 'ALCOHOL' by VTS based on DataChange editId 2347.	10/7/2018 11:23:11 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPHETAMINE	False	Question value " updated to 'METHAMPHETAMINE' by VTS based on DataChange, StateChange editId 2307.	10/7/2018 11:23:11 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPHETAMINE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NEGATIVE	False	- Empty -	10/8/2018 6:14:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPH	False	Question value " updated to 'METHAMPH' by VTS based on DataChange editId 2347.	10/7/2018 11:23:11 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPH	True	- Empty -	10/16/2018 12:37:01 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Week 6 **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 12/SEP/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Pregnancy Test

Was the pregnancy test performed? ☒ No ☒ Yes
Date of Collection 12/SEP/2018 DD/MON/YYYY(EN)
Test Type Urine
Pregnancy Test Result ☒ Negative ☒ Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	12/18/2018 2:29:49 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/21/2018 8:05:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	1/10/2019 3:31:14 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the pregnancy test performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
Y	False	- Empty -	12/21/2018 8:05:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	1/10/2019 3:31:14 PM CT	(b) (6)	CRA	001-Mathew	
If No, reason not performed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	False	- Empty -	12/21/2018 8:05:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:31:14 PM CT	(b) (6)	CRA	001-Mathew	

Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
12/SEP/2018	False	- Empty -	12/21/2018 8:05:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12/SEP/2018	True	- Empty -	1/10/2019 3:31:14 PM CT	(b) (6)	CRA	001-Mathew	

Test Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
URINE	False	- Empty -	12/21/2018 8:05:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
URINE	True	- Empty -	1/10/2019 3:31:14 PM CT	(b) (6)	CRA	001-Mathew	

Pregnancy Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	12/18/2018 2:29:49 PM CT	(b) (6)	Setup Administrator	001-Mathew	
NEGATIVE	False	- Empty -	12/21/2018 8:05:46 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	1/10/2019 3:31:14 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	End of Study
Visit Date	14/SEP/2018 DD/MON/YYYY(EN)
Was tobacco cessation information provided?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Visit Type	<input type="checkbox"/> End of Study <input type="checkbox"/> Early Termination
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	

Visit Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Study	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Study	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	

Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	

Visit Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	

Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	

Please specify if not done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Study	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Study	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:39:49 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Study **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 14/SEP/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Physical Examination - Symptom-driven

Did subject report any symptoms? ☒ No ☐ Yes

If No, reason not performed

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Did subject report any symptoms?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew	
If Yes, specify							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew	

Was the Physical Examination performed? 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew	

If No, reason not performed 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew	

Date of Examination 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew	

Were there any abnormal findings? 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew	

Body System							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew	

If Other, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew	

Specify Abnormal Findings							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew	

Specify Clinical Significance if Abnormal							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/18/2018 1:00:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:56:38 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Study **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 14/SEP/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Vital Signs				
Not Done		<input type="checkbox"/>		
Date of Measurements		<div>14/SEP/2018</div> <div>DD/MON/YYYY(EN)</div>		
Time of Measurements (24 Hour Clock)		<div>12:03</div> <div>HH:MM</div>		
Not Done	Result	Test Name	Unit	Clinical Significance
<input type="checkbox"/>	97.5	Temperature	F	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	65	Heart Rate	beats/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	14	Respiratory Rate	breaths/min	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	96	Systolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS
<input type="checkbox"/>	63	Diastolic Blood Pressure	mmHg	<input type="checkbox"/> NCS <input type="checkbox"/> CS

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew
Monitored	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew
Monitored	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Date of Measurements							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	False	(Date of Measurements should be equal to the visit date.) CORRECT AS IS	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	True	Correct as entered.	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	

Time of Measurements (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12:03	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
12:03	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HEIGHT	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
cm	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

cm	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
WEIGHT	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Unit							2
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BMI	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

BMI	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Unit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
kg/m^2	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
97.5	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
97.5	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMP	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Unit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
F	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
65	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
65	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
HR	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	

Unit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	

Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

Not Done							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	

Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESP	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Unit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BREATHS/MIN	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	

Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
96	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
96	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SYSBP	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Unit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	
Not Done							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
63	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
63	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DIABP	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Unit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mmHg	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:52:23 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/18/2018 1:51:12 PM CT	(b) (6)	TBMigration	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Study
Visit Date: 14/SEP/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Electrocardiogram

Was the ECG performed? ☒ No ☒ Yes

Date of ECG B 14/SEP/2018
DD/MON/YYYY(EN)

Time of ECG (24 hour clock) 11:48
HH:MM

Overall ECG Clinical Significance ☒ Normal ☒ Abnormal, Not Clinically Significant ☒ Abnormal, Clinically Significant

ECG Test Name	Test Results	Units
Heart Rate	65	Beats per Minute
RR	930	Millisecond
PR	146	Millisecond
QT	398	Millisecond
QRS	86	Millisecond
QTcF	409	Millisecond

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	10/16/2018 12:57:33 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	10/16/2018 1:02:54 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	11/9/2018 10:18:20 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Complete	11/13/2018 4:22:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Form: Electrocardiogram

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please add the EOS ECG to the subject packet.	10/16/2018 12:57:33 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	ecg in packet	11/13/2018 4:22:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Added.	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	

Was the ECG performed?

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	

What was the planned time point of the measurement?

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Study	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End of Study	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	

Date of ECG							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	False	(Date of ECG should be on the same day as the visit date.) correct as is	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	False	Site states data are correct.	11/9/2018 10:18:20 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
14/SEP/2018	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	

Time of ECG (24 hour clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
11:48	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
11:48	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	

Overall ECG Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NORMAL	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	

If Abnormal, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	

ECG Test Name							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ECG MEAN HEART RATE	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ECG MEAN HEART RATE	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
65	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
65	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BEATS/MIN	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EGHRMN	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
EGHRMN	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) RR DURATION	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) RR DURATION	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	

Test Results							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
930	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
930	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Units							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RRMEAN	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RRMEAN	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) PR DURATION	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) PR DURATION	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
146	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

146	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRMEAN	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRMEAN	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) QT DURATION	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) QT DURATION	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
398	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
398	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

msec	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTMEAN	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTMEAN	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) QRS DURATION	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUMMARY (MEAN) QRS DURATION	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
86	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
86	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QRSDUR	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QRSDUR	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
ECG Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTcF - Fridericia's Correction Formula	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QTcF - Fridericia's Correction Formula	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Results							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
409	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
409	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
msec	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:54:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:45:47 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Study **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 14/SEP/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Urine Drug Screen	
Was the Urine sample collected? <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
Date of Collection	<div>14/SEP/2018</div> <div>DD/MON/YYYY(EN)</div>
Test Name	Result
Opiates	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Amphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cocaine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Cannabinoids	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Alcohol	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive
Methamphetamine	<input checked="" type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/7/2018 11:23:36 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/8/2018 6:17:15 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Was the Urine sample collected?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	False	(Date of Drug Screen should be equal to the visit date.) CORRECT AS IS	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	True	Correct as entered.	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATES	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	

Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OPIATE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHETAMINE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
AMPHET	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

AMPHET	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
COCAINE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNABINOIDS	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NEGATIVE	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CANNAB	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ALCOHOL	False	Question value " updated to 'ALCOHOL' by VTS based on DataChange editId 2343.	10/7/2018 11:23:36 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ALCOHOL	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	

Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPHETAMINE	False	Question value " updated to 'METHAMPHETAMINE' by VTS based on DataChange, StateChange editId 2303.	10/7/2018 11:23:36 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPHETAMINE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NEGATIVE	False	- Empty -	10/8/2018 6:17:15 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NEGATIVE	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
METHAMPH	False	Question value " updated to 'METHAMPH' by VTS based on DataChange editId 2343.	10/7/2018 11:23:36 PM CT	(b) (6)	Setup Administrator	001-Mathew	
METHAMPH	True	- Empty -	10/16/2018 12:37:50 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** End of Study **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 14/SEP/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Subject Disposition

Did the subject complete the study? ☒ No ☒ Yes

Date of Completion or Discontinuation 14/SEP/2018
DD/MON/YYYY(EN)

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/17/2018 1:01:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	10/16/2018 12:57:12 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Did the subject complete the study?

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/17/2018 1:01:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:57:12 PM CT	(b) (6)	CRA	001-Mathew	

If No, reason for discontinuation

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:57:12 PM CT	(b) (6)	CRA	001-Mathew	

If Other, specify

1

Field							
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Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:57:12 PM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:57:12 PM CT	(b) (6)	CRA	001-Mathew	
If Non-compliance with Study Procedures, specify							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:57:12 PM CT	(b) (6)	CRA	001-Mathew	
If Physician Decision, specify							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:01:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:57:12 PM CT	(b) (6)	CRA	001-Mathew	
If Withdrawal by Subject, specify							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	9/17/2018 1:01:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:57:12 PM CT	(b) (6)	CRA	001-Mathew	
Date of Completion or Discontinuation							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:00:39 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	False	- Empty -	9/17/2018 1:01:56 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	True	- Empty -	10/16/2018 12:57:12 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Study
Visit Date: 14/SEP/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Chemistry

Accession Number 18419913S
Date of Collection 14/SEP/2018
DD/MON/YYYY(EN)
Time of Collection 12:08
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Albumin	4.2	g/dL	3.9	5		Yes No Recheck				
Alkaline Phosphatase	88	U/L	37	115		Yes No Recheck				
Alanine Aminotransferase	25	U/L	10	67		Yes No Recheck				
Aspartate Aminotransferase	19	U/L	14	48		Yes No Recheck				
Bilirubin	.4	mg/dL	.2	1.6		Yes No Recheck				
Carbon Dioxide	27.1	mmol/L	24	33.2		Yes No Recheck				
Creatinine	.50	mg/dL	.5	.9		Yes No Recheck				
Glucose	108	mg/dL	73	105	H	Yes No Recheck				
Potassium	4.6	mEq/L	3.7	5.2		Yes No Recheck				
Protein	6.4	g/dL	6.3	8.1		Yes No Recheck				
Sodium	140	mEq/L	135	143		Yes No Recheck				
Urea Nitrogen	12	mg/dL	6	17		Yes No Recheck				
Uric Acid	3.3	mg/dL	2.3	5.9		Yes No Recheck				

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:42 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Category							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CHEM	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CHEM	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18419913S	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18419913S	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
14/SEP/2018	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
14/SEP/2018	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

12:08	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12:08	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
ALB	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
ALB	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Albumin	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Albumin	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.2	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.9	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
ALP	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
ALP	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Alkaline Phosphatase	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Alkaline Phosphatase	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
88	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
88	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Units								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

U/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
U/L	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
37	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
37	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
115	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
115	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
ALT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
ALT	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Alanine Aminotransferase	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Alanine Aminotransferase	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
25	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
25	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	

Units								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
U/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
U/L	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
10	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
10	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
67	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
67	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 1								3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
AST	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
AST	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Aspartate Aminotransferase	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Aspartate Aminotransferase	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
19	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
19	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
U/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
U/L	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
14	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
14	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
48	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
48	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 1								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 3								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
BILI	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
BILI	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

Bilirubin	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Bilirubin	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.4	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.4	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.2	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.6	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.6	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CO2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CO2	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	

Test Name								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Carbon Dioxide	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Carbon Dioxide	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
27.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
27.1	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Units								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
mmol/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
mmol/L	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
24	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
24	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
33.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
33.2	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
CREAT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
CREAT	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Creatinine	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Creatinine	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.50	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.50	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.9	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Flag							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
GLUC	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
GLUC	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Glucose	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Glucose	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
108	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
108	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
73	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
73	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
105	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
105	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
H	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
H	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
N	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
N	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
K	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
K	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Potassium	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Potassium	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.6	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.6	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mEq/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mEq/L	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

3.7	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.7	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.2	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PROT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PROT	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Protein	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Protein	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
6.4	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
6.4	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
6.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
6.3	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
8.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
8.1	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 1								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
SODIUM	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
SODIUM	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Sodium	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Sodium	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
140	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
140	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mEq/L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mEq/L	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
135	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
135	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
143	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
143	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 3								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 4								11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
UEAN	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
UEAN	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Urea Nitrogen	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Urea Nitrogen	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

12	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Units							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
mg/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
mg/dL	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
6	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
6	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
17	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
17	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
URATE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
URATE	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Uric Acid	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Uric Acid	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	

Test Result								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
3.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
3.3	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Units								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
mg/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
mg/dL	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
2.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
2.3	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
5.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
5.9	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		

- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:24 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:52 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b)(6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b)(6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b)(6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b)(6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b)(6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b)(6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b)(6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Study
Visit Date: 14/SEP/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Hematology

Accession Number 18419919B
Date of Collection 14/SEP/2018
DD/MON/YYYY(EN)
Time of Collection 12:08
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Basophils	0.0	Thou/uL	0	.1		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Basophils/Leukocytes	.3	%	0	2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Eosinophils	.2	Thou/uL	0	.5		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Eosinophils/Leukocytes	2.1	%	.5	7.4		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Hematocrit	40.4	%	35.3	47		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Hemoglobin	13.0	g/dL	12	15.9		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Lymphocytes	3.0	Thou/uL	1.1	3.2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Lymphocytes/Leukocytes	30.3	%	15.8	45.8		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Monocytes	.4	Thou/uL	.3	.9		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Monocytes/Leukocytes	4.3	%	4.9	12.8	L	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Neutrophils	6.1	Thou/uL	1.6	7.7		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Neutrophils/Leukocytes	62.8	%	38.4	74.2		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Platelets	289	Thou/uL	155	361		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Erythrocytes	4.52	Mil/uL	3.95	5.21		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Leukocytes	9.8	Thou/uL	3.7	11.5		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:42 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HEME	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HEME	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18419919B	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18419919B	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
14/SEP/2018	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
14/SEP/2018	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12:08	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

12:08	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
BASO	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
BASO	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Basophils	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Basophils	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
0.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0.0	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

0	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.1	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
BASOLE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
BASOLE	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Basophils/Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Basophils/Leukocytes	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.3	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
2	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
EOS	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
EOS	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Eosinophils	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Eosinophils	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.2	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
0	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
EOSLE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
EOSLE	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Eosinophils/Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Eosinophils/Leukocytes	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
2.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
2.1	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.5	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.4	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.4	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HCT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HCT	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hematocrit	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hematocrit	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
40.4	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
40.4	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
35.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
35.3	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
47	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
47	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
HGB	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
HGB	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Hemoglobin	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Hemoglobin	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
13.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
13.0	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
g/dL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
g/dL	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
15.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15.9	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
LYM	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
LYM	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Lymphocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Lymphocytes	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.0	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
1.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
1.1	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Upper Limit								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
3.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
3.2	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Flag								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew		
Clinical Significance								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 1								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew		
Lab Comment 2								7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew		

Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
LYMLE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
LYMLE	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Lymphocytes/Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Lymphocytes/Leukocytes	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
30.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
30.3	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	

Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
15.8	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
15.8	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
45.8	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
45.8	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
MONO	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
MONO	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Monocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Monocytes	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.4	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.4	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

Thou/uL	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.3	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
.9	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
MONOLE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
MONOLE	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Monocytes/Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Monocytes/Leukocytes	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.3	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.3	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

%	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.9	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.9	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
12.8	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
12.8	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
L	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
L	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
N	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
N	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEUT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEUT	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Neutrophils	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Neutrophils	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
6.1	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
6.1	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.6	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.6	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
7.7	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
7.7	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							11
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEUTLE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEUTLE	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Neutrophils/Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Neutrophils/Leukocytes	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
62.8	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
62.8	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
%	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
%	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
38.4	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
38.4	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
74.2	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
74.2	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							12
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PLAT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PLAT	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Platelets	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Platelets	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
289	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
289	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
155	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
155	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
361	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
361	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							13
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							13
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
RBC	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
RBC	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Erythrocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Erythrocytes	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
4.52	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
4.52	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							14
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Mil/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Mil/uL	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.95	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.95	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.21	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.21	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							14

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							14
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
WBC	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
WBC	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Leukocytes	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Leukocytes	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
9.8	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
9.8	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Units							15

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Thou/uL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Thou/uL	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
3.7	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
3.7	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
11.5	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
11.5	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							15
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:26:44 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:49:56 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name: End of Study
Visit Date: 14/SEP/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Lab Import - Urinalysis

Accession Number 18419879U
Date of Collection 14/SEP/2018
DD/MON/YYYY(EN)
Time of Collection 11:18
HH:MM

Test Results

Test Name	Test Result	Units	Reference Range Lower Limit	Reference Range Upper Limit	Reference Range Flag	Clinical Significance	Lab Comment 1	Lab Comment 2	Lab Comment 3	Lab Comment 4
Ketones	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Leukocyte Esterase	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Nitrite	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Occult Blood	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
pH	8.0		5.0	8.0		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Specific Gravity	1.005		1.005	1.030		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urine Bilirubin	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urine Glucose	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urine Protein	NEGATIVE		NEG, TRACE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				
Urobilinogen	NEGATIVE		NEGATIVE			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Recheck				

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Incomplete	1/16/2019 1:46:42 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew
Complete	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Catgeory							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UA	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UA	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Accession Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
18419879U	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
18419879U	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Date of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
14/SEP/2018	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
14/SEP/2018	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Time of Collection							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
11:18	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
11:18	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Did the Subject fast 8 hours prior to collection?							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
KETONES	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
KETONES	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Ketones	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Ketones	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Units							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 4								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:46 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew		
Test Code								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
LEUKASE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
LEUKASE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew		
Test Name								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
Leukocyte Esterase	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
Leukocyte Esterase	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew		
Test Result								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew		
Units								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew		
Reference Range Lower Limit								2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew		
NEG, TRACE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt	

NEG, TRACE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							2
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NITRITE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NITRITE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Nitrite	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Nitrite	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Units							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							3
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
OCCBLD	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
OCCBLD	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Occult Blood	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Occult Blood	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Units							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							4

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 3							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							4
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
PH	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
PH	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
pH	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
pH	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
8.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
8.0	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Units							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
5.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
5.0	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
8.0	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
8.0	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							5
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
SPGRAV	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
SPGRAV	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Specific Gravity	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Specific Gravity	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.005	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.005	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Units							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.005	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.005	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
1.030	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
1.030	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							6
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UBILI	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UBILI	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Bilirubin	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Bilirubin	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Units							7

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 2							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							7
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UGLUC	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UGLUC	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Glucose	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Glucose	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt

NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Units							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	

- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							8
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UPROT	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UPROT	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urine Protein	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urine Protein	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Units							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEG, TRACE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEG, TRACE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 1							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							9
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Code							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
UROBIL	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
UROBIL	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Name							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
Urobilinogen	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
Urobilinogen	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Test Result							10

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Units							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Lower Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
NEGATIVE	False	- Empty -	1/16/2019 1:46:44 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	File Import 001_lab_2019-01-16.txt
NEGATIVE	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Upper Limit							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Reference Range Flag							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Clinical Significance							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	

Lab Comment 1							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 2							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 3							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	
Lab Comment 4							10
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	1/16/2019 1:45:56 PM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew	
- Empty -	False	- Empty -	1/16/2019 2:27:09 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	1/28/2019 4:50:00 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Visit	
Visit	
Visit Not Done	<input type="checkbox"/>
Visit Name	
Visit Date	21/SEP/2018 DD/MON/YYYY (EN)
Visit Number	
Did the subject report any changes in medical history(ies) since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new AEs or any changes to AEs since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	9/28/2018 10:35:53 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	9/28/2018 10:36:32 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew
Complete	11/19/2018 11:25:24 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	11/28/2018 7:11:50 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Visit Not Done							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Reason Not Done							1
	Field						

Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Visit Name							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Visit Date							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
21/SEP/2018	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
21/SEP/2018	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Visit Number							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Was tobacco cessation information provided?							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/16/2018 12:40:59 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Please specify if not done							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Visit Type							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Earliest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Latest Expected Visit Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Planned Study Day of Visit							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Upcoming Visit Offset							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Visit Caption							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any changes in medical history(ies) since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Please confirm if this correct as a SAE occurred stating on 15-Sep-2018.	9/28/2018 10:35:53 AM CT	(b) (6)	CRA	001-Mathew	
N	False	Incorrect query.	9/28/2018 10:36:32 AM CT	(b) (6)	CRA	001-Mathew	
N	True	- Empty -	10/16/2018 12:45:13 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new AEs or any changes to AEs since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

N	False	Please confirm if this correct as a SAE occurred stating on 15-Sep-2018.	9/28/2018 10:36:32 AM CT	(b) (6)	CRA	001-Mathew	
Y	False	UPDATED	11/19/2018 11:25:24 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Transcription Error	11/19/2018 11:25:24 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	Updated.	11/28/2018 7:11:50 PM CT	(b) (6)	CRA	001-Mathew	
Did the subject report any new concomitant medication or any changes to concomitant medication since the last visit?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/24/2018 2:57:59 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Please confirm if this correct as a SAE occurred stating on 15-Sep-2018.	9/28/2018 10:36:32 AM CT	(b) (6)	CRA	001-Mathew	
Y	False	UPDATED	11/19/2018 11:25:24 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Transcription Error	11/19/2018 11:25:24 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	Updated.	11/28/2018 7:11:50 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** **iCRF Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** 21/SEP/2018 **Subject Initials:**
Subject Number: 001023 **Current Time:**

Physical Examination - Symptom-driven	
Did subject report any symptoms?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
If Yes, specify	SUBARACHNOID HEMORRHAGE
Was the Physical Examination performed?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
If No, reason not performed	LOST TO FOLLOW UP

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	9/28/2018 10:36:46 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	10/16/2018 12:45:18 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	12/4/2018 7:44:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	12/4/2018 8:44:38 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/12/2018 10:01:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	1/10/2019 3:34:14 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	1/10/2019 3:34:38 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	1/10/2019 3:34:50 PM CT	(b) (6)	CRA	001-Mathew
Monitored	2/7/2019 11:24:58 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Did subject report any symptoms?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Please confirm if this correct as a SAE occurred stating on 15-Sep-2018.	9/28/2018 10:36:46 AM CT	(b) (6)	CRA	001-Mathew	
Y	False	updated	12/4/2018 7:44:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Transcription Error	12/4/2018 7:44:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Updated.	12/4/2018 8:44:38 PM CT	(b) (6)	CRA	001-Mathew	
Y	True	- Empty -	1/10/2019 3:34:50 PM CT	(b) (6)	CRA	001-Mathew	

If Yes, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Transcription Error	12/4/2018 7:44:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	1/10/2019 3:34:50 PM CT	(b) (6)	CRA	001-Mathew	

Was the Physical Examination performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Transcription Error	12/4/2018 7:44:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	1/10/2019 3:34:50 PM CT	(b) (6)	CRA	001-Mathew	

If No, reason not performed							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/4/2018 7:44:29 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Please respond.	12/4/2018 8:44:38 PM CT	(b) (6)	CRA	001-Mathew	
LOST TO FOLLOW UP	False	Transcription Error	12/12/2018 10:01:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LOST TO FOLLOW UP	False	UPDATED	12/12/2018 10:01:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
LOST TO FOLLOW UP	False	Completed.	1/10/2019 3:34:14 PM CT	(b) (6)	CRA	001-Mathew	
LOST TO FOLLOW UP	True	- Empty -	2/7/2019 11:24:58 PM CT	(b) (6)	CRA	001-Mathew	

Date of Examination							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:24:58 PM CT	(b) (6)	CRA	001-Mathew	

Were there any abnormal findings?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:24:58 PM CT	(b) (6)	CRA	001-Mathew	

Body System							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:24:58 PM CT	(b) (6)	CRA	001-Mathew	

If Other, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:24:58 PM CT	(b) (6)	CRA	001-Mathew	

Specify Abnormal Findings							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:24:58 PM CT	(b) (6)	CRA	001-Mathew	

Specify Clinical Significance if Abnormal							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 2:58:05 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 11:24:58 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date: 21/SEP/2018
Current Time:

iCRF Status: Signed Locked
Subject Initials:

Phone Call

Date of Call

21/SEP/2018
 DD/MON/YYYY
 (EN)

Was tobacco cessation information provided?

☒ No ☒ Yes

Did Subject need to return to the clinic for a symptom driven physical exam?

☒ No ☒ Yes

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/24/2018 2:58:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	9/28/2018 10:37:02 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	10/16/2018 12:45:34 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/12/2018 9:01:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	1/10/2019 3:34:32 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/1/2019 2:51:47 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/5/2019 7:48:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	2/6/2019 6:04:38 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/14/2019 8:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/14/2019 9:15:23 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Date of Call							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
21/SEP/2018	False	- Empty -	9/24/2018 2:58:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
21/SEP/2018	True	- Empty -	10/16/2018 12:45:34 PM CT	(b) (6)	CRA	001-Mathew	

Was tobacco cessation information provided?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	9/24/2018 2:58:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	10/16/2018 12:45:34 PM CT	(b) (6)	CRA	001-Mathew	
Did Subject need to return to the clinic for a symptom driven physical exam?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/24/2018 2:58:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Please confirm if this correct as a SAE occurred stating on 15-Sep-2018.	9/28/2018 10:37:02 AM CT	(b) (6)	CRA	001-Mathew	
N	False	subject is lost to follow up	12/12/2018 9:01:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Will re-issue query.	2/1/2019 2:51:47 PM CT	(b) (6)	CRA	001-Mathew	
N	False	Please confirm if this correct as the source documents that this call occurred.	2/1/2019 2:51:47 PM CT	(b) (6)	CRA	001-Mathew	
N	False	subject did not return for physical, subject was lost to follow up	2/5/2019 7:48:50 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Will re-issue query.	2/6/2019 6:04:38 PM CT	(b) (6)	CRA	001-Mathew	
N	False	Should a comment be added to the source explaining why the subject was not required to return for a PE as the subject had a SAE prior to this call?	2/6/2019 6:04:38 PM CT	(b) (6)	CRA	001-Mathew	
N	False	information added to progress notes	2/14/2019 8:35:05 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	Clarified in the progress notes.	2/14/2019 9:15:23 AM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** iCRF **Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** **Subject Initials:**
Subject Number: 001023 **Current Time:**

Adverse Events

Were any Adverse Events experienced? ☒ No ☒ Yes

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	9/28/2018 10:37:33 AM CT	(b) (6)	CRA	001-Mathew
Complete	11/19/2018 10:58:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:38:04 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

Form: Adverse Events

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please add the SAE data once entered into ClinQuick.	9/28/2018 10:37:33 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	ADDED	11/19/2018 10:58:28 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Added.	12/4/2018 7:38:04 PM CT	(b) (6)	CRA	001-Mathew	

Were any Adverse Events experienced?

1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	12/4/2018 7:38:04 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

AE-TEMPORAL HEADACHE-16/AUG/2018

AE Number	1
Adverse Event	TEMPORAL HEADACHE
Onset Date	16/AUG/2018 DD/MON/YYYY(EN)
Onset Time (24 Hour Clock)	14:30 HH:MM
Ongoing	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Resolved Date	17/AUG/2018 DD/MON/YYYY(EN)
Resolved Time (24 Hour Clock)	15:00 HH:MM
Frequency	Continuous
Severity	Moderate
Serious Event?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Outcome	Resolved
Action taken with study product	Not Changed
Relationship to study product	Possible
What other action was taken in response to this adverse event?	CONCOMITANT MEDICATION GIVEN
Verbatim Term	TEMPORAL HEADACHE
MedDRA LLT Name	Temporal headache
MedDRA LLT Code	10043208
MedDRA PT Name	Headache
MedDRA PT Code	10019211
MedDRA HLT Name	Headaches NEC
MedDRA HLT Code	10019233
MedDRA HLGT Name	Headaches
MedDRA HLGT Code	10019231
MedDRA SOC Name	Nervous system disorders
MedDRA SOC Code	10029205

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	8/28/2018 5:29:47 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/7/2018 10:22:29 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:19:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14:30	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14:30	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/AUG/2018	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
17/AUG/2018	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15:00	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15:00	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MODERATE	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MODERATE	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NOT CHANGED	False	Transcription Error	10/9/2018 1:19:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONCOMITANT MEDICATION GIVEN	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONCOMITANT MEDICATION GIVEN	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE	False	Question value " updated to 'TEMPORAL HEADACHE' by VTS based on DataChange editId 176.	8/28/2018 5:29:47 PM CT	(b) (6)	Setup Administrator	001-Mathew	
TEMPORAL HEADACHE	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Temporal headache	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Temporal headache	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Temporal headache	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10043208	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10043208	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
10043208	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Headache	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Headache	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Headache	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10019211	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10019211	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
10019211	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
Headaches NEC	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Headaches NEC	True	- Empty -	12/4/2018 7:40:07 PM CT	(b)(6)	CRA	001-Mathew	
Headaches NEC	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
10019233	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10019233	True	- Empty -	12/4/2018 7:40:07 PM CT	(b)(6)	CRA	001-Mathew	
10019233	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
Headaches	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Headaches	True	- Empty -	12/4/2018 7:40:07 PM CT	(b)(6)	CRA	001-Mathew	
Headaches	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
10019231	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10019231	True	- Empty -	12/4/2018 7:40:07 PM CT	(b)(6)	CRA	001-Mathew	
10019231	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
Nervous system disorders	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Nervous system disorders	True	- Empty -	12/4/2018 7:40:07 PM CT	(b)(6)	CRA	001-Mathew	
Nervous system disorders	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
10029205	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10029205	True	- Empty -	12/4/2018 7:40:07 PM CT	(b)(6)	CRA	001-Mathew	
10029205	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:33:32 PM CT	(b)(6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:40:07 PM CT	(b)(6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE_2018/08/16_MODERATE_CONTINUOUS_N_ _	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE_2018/08/16_MODERATE_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE_2018/08/16_MODERATE_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:27:21 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE_2018/08/16_MODERATE_CONTINUOUS_N_ _	False	- Empty -	8/24/2018 3:28:29 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE_2018/08/16_MODERATE_CONTINUOUS_N_RESOLVED_POSSIBLE	False	- Empty -	9/10/2018 2:33:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE_2018/08/16_MODERATE_CONTINUOUS_N_RESOLVED_POSSIBLE	True	- Empty -	12/4/2018 7:40:07 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN	Visit Name:	iCRF Status: Signed Locked
Subject Caption: 001023	Visit Date:	Subject Initials:
Subject Number: 001023	Current Time:	

AE-OCCIPITAL HEADACHE-19/AUG/2018		
AE Number	2	
Adverse Event	OCCIPITAL HEADACHE	
Onset Date	19/AUG/2018 DD/MON/YYYY(EN)	
Onset Time (24 Hour Clock)	18:30 HH:MM	
Ongoing	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
Resolved Date	02/SEP/2018 DD/MON/YYYY(EN)	
Resolved Time (24 Hour Clock)	13:30 HH:MM	
Frequency	Intermittent	
Severity	Mild	
Serious Event?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
Outcome	Resolved	
Action taken with study product	Not Changed	
Relationship to study product	Possible	
What other action was taken in response to this adverse event?	NONE	
Verbatim Term	OCCIPITAL HEADACHE	
MedDRA LLT Name	Occipital headache	
MedDRA LLT Code	10048968	
MedDRA PT Name	Headache	
MedDRA PT Code	10019211	
MedDRA HLT Name	Headaches NEC	
MedDRA HLT Code	10019233	
MedDRA HLGT Name	Headaches	
MedDRA HLGT Code	10019231	
MedDRA SOC Name	Nervous system disorders	
MedDRA SOC Code	10029205	

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	10/7/2018 10:22:35 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:20:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History

AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	

Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	

Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19/AUG/2018	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
19/AUG/2018	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	

Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18:30	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
18:30	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	

Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	

Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/SEP/2018	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/SEP/2018	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	

Resolved Time (24 Hour Clock)							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:30	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
13:30	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTERMITTENT	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTERMITTENT	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NOT CHANGED	False	Transcription Error	10/9/2018 1:20:02 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NOT CHANGED	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew
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Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
POSSIBLE	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	

What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NONE	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	

Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE	False	Question value " updated to 'OCCIPITAL HEADACHE' by VTS based on DataChange editId 176.	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
OCCIPITAL HEADACHE	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	

MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
Occipital headache	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Occipital headache	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Occipital headache	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
10048968	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10048968	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
10048968	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
Headache	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Headache	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Headache	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
10019211	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10019211	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
10019211	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
Headaches NEC	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Headaches NEC	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Headaches NEC	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
10019233	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10019233	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
10019233	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
Headaches	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Headaches	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Headaches	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
10019231	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10019231	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
10019231	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	
Nervous system disorders	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Nervous system disorders	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Nervous system disorders	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:04 PM CT	(b) (6)	Setup Administrator	001-Mathew	

10029205	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10029205	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
10029205	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE_2018/08/19_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE_2018/08/19_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/10/2018 2:33:49 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE_2018/08/19_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	False	- Empty -	9/10/2018 2:35:03 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OCCIPITAL HEADACHE_2018/08/19_MILD_INTERMITTENT_N_RESOLVED_POSSIBLE	True	- Empty -	12/4/2018 7:39:24 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

AE-TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE-14/SEP/2018	
AE Number	3
Adverse Event	TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE
Onset Date	14/SEP/2018 DD/MON/YYYY(EN)
Onset Time (24 Hour Clock)	09:50 HH:MM
Ongoing	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Resolved Date	<input checked="" type="checkbox"/> 15/SEP/2018 DD/MON/YYYY(EN)
Resolved Time (24 Hour Clock)	14:00 HH:MM
Frequency	Intermittent
Severity	Mild
Serious Event?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Outcome	Resolved
Action taken with study product	Not Changed
Relationship to study product	Not related
What other action was taken in response to this adverse event?	ICE BAG GIVEN AT 10:50 ON 14SEP2018
Verbatim Term	TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE
MedDRA LLT Name	Venipuncture site pain
MedDRA LLT Code	10048823
MedDRA PT Name	Vessel puncture site pain
MedDRA PT Code	10066951
MedDRA HLT Name	Administration site reactions NEC
MedDRA HLT Code	10057196
MedDRA HLGT Name	Administration site reactions
MedDRA HLGT Code	10001316
MedDRA SOC Name	General disorders and administration site conditions
MedDRA SOC Code	10018065

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	9/17/2018 5:08:05 PM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	9/24/2018 2:59:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew

Complete	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	10/7/2018 10:22:35 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	10/9/2018 1:20:15 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	11/13/2018 1:53:24 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Partial Monitored	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/5/2018 7:19:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/5/2018 7:19:18 AM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	12/5/2018 10:54:40 AM CT	(b) (6)	CRA	001-Mathew
Complete	12/6/2018 11:34:20 AM CT	kcheek	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/17/2018 2:20:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Complete	12/17/2018 2:22:15 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Complete	12/17/2018 2:34:50 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/17/2018 2:34:55 PM CT	(b) (6)	Setup Administrator	001-Mathew
Complete	12/19/2018 4:15:38 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Monitored	1/10/2019 3:34:58 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
AE Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Adverse Event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW	False	Per the source, the name of this AE is Tenderness at Right Antecubital. Please update the CRF.	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL	False	updated	12/5/2018 7:19:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL	False	Transcription Error	12/5/2018 7:19:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL	True	Updated.	12/5/2018 10:54:40 AM CT	(b) (6)	CRA	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL	True	MEDICAL CODING: Is this at a venipuncture site? If yes, please update verbatim accordingly. Thanks!	12/6/2018 11:34:20 AM CT	kcheek	Clinical Research Coordinator (CRC)	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL	False	Please clarify if this was at an injection or venipuncture site.	12/17/2018 2:20:54 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE	False	Transcription Error	12/17/2018 2:34:50 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE	False	UPDATED TERM	12/17/2018 2:34:50 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE	False	Updated. Query closed.	12/19/2018 4:15:38 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE	True	- Empty -	1/10/2019 3:34:58 PM CT	(b) (6)	CRA	001-Mathew	
Onset Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14/SEP/2018	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
09:50	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
09:50	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/24/2018 2:59:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	False	- Empty -	9/24/2018 2:59:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	False	(The Stop Date should be prior to or equal to the Date of Completion or Discontinuation.) correct as is	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	False	Data verified by site.	11/13/2018 1:53:24 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
15/SEP/2018	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14:00	False	- Empty -	9/24/2018 2:59:25 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
14:00	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTERMITTENT	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTERMITTENT	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	

Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
MILD	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOSE NOT CHANGED	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	10/7/2018 9:58:39 PM CT	(b) (6)	TBMigration	001-Mathew	
NOT CHANGED	False	Transcription Error	10/9/2018 1:20:15 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT RELATED	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

NOT RELATED	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
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What other action was taken in response to this adverse event?							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ICE BAG GIVEN AT 10:50 ON 14SEP2018	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ICE BAG GIVEN AT 10:50 ON 14SEP2018	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	

Verbatim Term							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW	False	Question value " updated to 'TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW' by VTS based on DataChange editId 176.	9/17/2018 5:08:05 PM CT	(b) (6)	Setup Administrator	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL	False	Question value 'TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW' updated to 'TENDERNESS AT RIGHT ANTECUBITAL' by VTS based on DataChange editId 1738.	12/5/2018 7:19:18 AM CT	(b) (6)	Setup Administrator	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL	True	- Empty -	12/5/2018 10:54:40 AM CT	(b) (6)	CRA	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE	False	Question value 'TENDERNESS AT RIGHT ANTECUBITAL' updated to 'TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE' by VTS based on DataChange editId 1738.	12/17/2018 2:34:55 PM CT	(b) (6)	Setup Administrator	001-Mathew	
TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE	True	- Empty -	1/10/2019 3:34:58 PM CT	(b) (6)	CRA	001-Mathew	

MedDRA LLT Name							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Venipuncture site pain	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
Venipuncture site pain	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 7:20:01 AM CT	tmsystem	TBRole	001-Mathew	
Venipuncture site pain	True	- Empty -	12/18/2018 6:02:01 AM CT	tmsystem	TBRole	001-Mathew	
Venipuncture site pain	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

MedDRA LLT Code							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10048823	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew	
10048823	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 7:20:01 AM CT	tmsystem	TBRole	001-Mathew	
10048823	True	- Empty -	12/18/2018 6:02:01 AM CT	tmsystem	TBRole	001-Mathew	
10048823	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew	

MedDRA PT Name								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
Vessel puncture site pain	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
Vessel puncture site pain	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew		
- Empty -	True	- Empty -	12/5/2018 7:20:01 AM CT	tmsystem	TBRole	001-Mathew		
Vessel puncture site pain	True	- Empty -	12/18/2018 6:02:01 AM CT	tmsystem	TBRole	001-Mathew		
Vessel puncture site pain	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA PT Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
10066951	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
10066951	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew		
- Empty -	True	- Empty -	12/5/2018 7:20:01 AM CT	tmsystem	TBRole	001-Mathew		
10066951	True	- Empty -	12/18/2018 6:02:01 AM CT	tmsystem	TBRole	001-Mathew		
10066951	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA HLT Name								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
Administration site reactions NEC	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
Administration site reactions NEC	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew		
- Empty -	True	- Empty -	12/5/2018 7:20:01 AM CT	tmsystem	TBRole	001-Mathew		
Administration site reactions NEC	True	- Empty -	12/18/2018 6:02:01 AM CT	tmsystem	TBRole	001-Mathew		
Administration site reactions NEC	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA HLT Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
10057196	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
10057196	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew		
- Empty -	True	- Empty -	12/5/2018 7:20:01 AM CT	tmsystem	TBRole	001-Mathew		
10057196	True	- Empty -	12/18/2018 6:02:01 AM CT	tmsystem	TBRole	001-Mathew		
10057196	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA HLGT Name								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
Administration site reactions	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
Administration site reactions	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew		
- Empty -	True	- Empty -	12/5/2018 7:20:01 AM CT	tmsystem	TBRole	001-Mathew		
Administration site reactions	True	- Empty -	12/18/2018 6:02:01 AM CT	tmsystem	TBRole	001-Mathew		
Administration site reactions	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		

MedDRA HLGT Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
10001316	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
10001316	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew		
- Empty -	True	- Empty -	12/5/2018 7:20:01 AM CT	tmsystem	TBRole	001-Mathew		
10001316	True	- Empty -	12/18/2018 6:02:01 AM CT	tmsystem	TBRole	001-Mathew		
10001316	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA SOC Name								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
General disorders and administration site conditions	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
General disorders and administration site conditions	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew		
- Empty -	True	- Empty -	12/5/2018 7:20:01 AM CT	tmsystem	TBRole	001-Mathew		
General disorders and administration site conditions	True	- Empty -	12/18/2018 6:02:01 AM CT	tmsystem	TBRole	001-Mathew		
General disorders and administration site conditions	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
MedDRA SOC Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
10018065	False	- Empty -	9/24/2018 11:53:01 AM CT	tmsystem	TBRole	001-Mathew		
10018065	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew		
- Empty -	True	- Empty -	12/5/2018 7:20:01 AM CT	tmsystem	TBRole	001-Mathew		
10018065	True	- Empty -	12/18/2018 6:02:01 AM CT	tmsystem	TBRole	001-Mathew		
10018065	True	- Empty -	12/18/2018 10:04:01 AM CT	tmsystem	TBRole	001-Mathew		
Not a true data. Flag is used for New SAE Notification.								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001-Mathew		
Not a true data. Concatenated field used for Updated SAE Notification.								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW_2018/09/14_MILD_INTERMITTENT_N_	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		

TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	False	- Empty -	12/5/2018 7:19:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	True	- Empty -	12/5/2018 10:54:40 AM CT	(b) (6)	CRA	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	False	- Empty -	12/17/2018 2:34:50 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	True	- Empty -	1/10/2019 3:34:58 PM CT	(b) (6)	CRA	001- Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	9/17/2018 1:02:47 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW_2018/09/14_MILD_INTERMITTENT_N_	False	- Empty -	9/17/2018 1:04:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	False	- Empty -	9/24/2018 3:02:06 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL DUE TO BLOOD DRAW_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	True	- Empty -	12/4/2018 7:41:45 PM CT	(b) (6)	CRA	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	False	- Empty -	12/5/2018 7:19:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	True	- Empty -	12/5/2018 10:54:40 AM CT	(b) (6)	CRA	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	False	- Empty -	12/17/2018 2:34:50 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE_2018/09/14_MILD_INTERMITTENT_N_RESOLVED_NOT RELATED	True	- Empty -	1/10/2019 3:34:58 PM CT	(b) (6)	CRA	001- Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

AE-SUBARACHNOID HEMORRHAGE-15/SEP/2018	
AE Number	4
Adverse Event	SUBARACHNOID HEMORRHAGE
Onset Date	<div>B</div> 15/SEP/2018 DD/MON/YYYY(EN)
Onset Time (24 Hour Clock)	UNK:UNK HH:MM
Ongoing	<input checked="" type="radio"/> No <input type="radio"/> Yes
Resolved Date	<div>B</div> 02/OCT/2018 DD/MON/YYYY(EN)
Resolved Time (24 Hour Clock)	UNK:UNK HH:MM
Frequency	Continuous
Severity	Severe
Serious Event?	<input checked="" type="radio"/> No <input type="radio"/> Yes
Serious Criteria	
A congenital anomaly/birth defect	<input checked="" type="radio"/> No <input type="radio"/> Yes
A persistent or significant disability/incapacity	<input checked="" type="radio"/> No <input type="radio"/> Yes
In-patient hospitalization or prolongation of existing hospitalization	<input checked="" type="radio"/> No <input type="radio"/> Yes
Admission Date	15/SEP/2018 DD/MON/YYYY(EN)
Discharge Date	02/OCT/2018 DD/MON/YYYY(EN)
A life-threatening adverse study experience	<input checked="" type="radio"/> No <input type="radio"/> Yes
Important medical event	<input checked="" type="radio"/> No <input type="radio"/> Yes
Death	<input checked="" type="radio"/> No <input type="radio"/> Yes
Outcome	Resolved
Action taken with study product	Not Changed
Relationship to study product	Not related
What other action was taken in response to this adverse event?	CON MEDS

Verbatim Term	SUBARACHNOID HEMORRHAGE
MedDRA LLT Name	Subarachnoid hemorrhage
MedDRA LLT Code	10042320
MedDRA PT Name	Subarachnoid haemorrhage
MedDRA PT Code	10042316
MedDRA HLT Name	Cerebral injuries NEC
MedDRA HLT Code	10052638
MedDRA HLGT Name	Injuries NEC
MedDRA HLGT Code	10022114
MedDRA SOC Name	Injury, poisoning and procedural complications
MedDRA SOC Code	10022117

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:09:27 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	12/14/2018 6:40:40 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	12/17/2018 2:24:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	1/10/2019 3:39:37 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	1/17/2019 12:49:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	2/6/2019 5:39:34 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/11/2019 9:26:07 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/11/2019 9:26:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History								
Question Audit History								
AE Number								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
4	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
4	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew		
Adverse Event								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
SUBARACHNOID HEMORRHAGE	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
SUBARACHNOID HEMORRHAGE	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew		
Onset Date								1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	False	(The Onset Date should be prior to or equal to the Date of Completion or Discontinuation.) correct as is	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	False	Correct as entered.	1/10/2019 3:39:37 PM CT	(b) (6)	CRA	001-Mathew	
15/SEP/2018	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Onset Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Resolved Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	(The Stop Date should be prior to or equal to the Date of Completion or Discontinuation.) correct as is	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	Correct as entered.	1/10/2019 3:39:37 PM CT	(b) (6)	CRA	001-Mathew	
02/OCT/2018	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Resolved Time (24 Hour Clock)							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Severity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SEVERE	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SEVERE	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Serious Event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Please select yes and update this AE per the SAE report and source.	12/14/2018 6:40:40 PM CT	(b) (6)	CRA	001-Mathew	
Y	False	- Empty -	12/17/2018 2:24:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	updated	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Updated.	1/10/2019 3:39:37 PM CT	(b) (6)	CRA	001-Mathew	
Y	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
A congenital anomaly/birth defect							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Please change to no per the source as the subject was hospitalized for this SAE.	1/10/2019 3:39:37 PM CT	(b) (6)	CRA	001-Mathew	
N	False	updated	1/17/2019 12:49:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Transcription Error	1/17/2019 12:49:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Updated.	2/6/2019 5:39:34 PM CT	(b) (6)	CRA	001-Mathew	
N	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
A persistent or significant disability/incapacity							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
In-patient hospitalization or prolongation of existing hospitalization							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Admission Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Please complete.	1/10/2019 3:39:37 PM CT	(b) (6)	CRA	001-Mathew	

15/SEP/2018	False	updated	2/11/2019 9:26:07 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	True	Completed.	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Discharge Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Please complete.	1/10/2019 3:39:37 PM CT	(b) (6)	CRA	001-Mathew	
02/OCT/2018	False	updated	2/11/2019 9:26:07 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	True	Completed.	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
A life-threatening adverse study experience							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Please change to no per the source as the subject was hospitalized for this SAE.	1/10/2019 3:39:37 PM CT	(b) (6)	CRA	001-Mathew	
N	False	updated	1/17/2019 12:49:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Transcription Error	1/17/2019 12:49:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Updated.	2/6/2019 5:39:34 PM CT	(b) (6)	CRA	001-Mathew	
N	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Important medical event							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Y	False	Please change to no per the source as the subject was hospitalized for this SAE.	1/10/2019 3:39:37 PM CT	(b) (6)	CRA	001-Mathew	
N	False	updated	1/17/2019 12:49:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Transcription Error	1/17/2019 12:49:58 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Updated.	2/6/2019 5:39:34 PM CT	(b) (6)	CRA	001-Mathew	
N	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Date of Death							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:26:07 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Was an autopsy performed?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/11/2019 9:26:07 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Outcome							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
RESOLVED	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Action taken with study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT CHANGED	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Relationship to study product							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT RELATED	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NOT RELATED	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
What other action was taken in response to this adverse event?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CON MEDS	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CON MEDS	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 1738.	11/19/2018 11:09:27 AM CT	(b) (6)	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

Subarachnoid hemorrhage	False	- Empty -	11/20/2018 7:02:00 AM CT	tmsystem	TBRole	001-Mathew	
Subarachnoid hemorrhage	False	- Empty -	12/18/2018 10:04:02 AM CT	tmsystem	TBRole	001-Mathew	
Subarachnoid hemorrhage	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
MedDRA LLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10042320	False	- Empty -	11/20/2018 7:02:00 AM CT	tmsystem	TBRole	001-Mathew	
10042320	False	- Empty -	12/18/2018 10:04:02 AM CT	tmsystem	TBRole	001-Mathew	
10042320	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
MedDRA PT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Subarachnoid haemorrhage	False	- Empty -	11/20/2018 7:02:00 AM CT	tmsystem	TBRole	001-Mathew	
Subarachnoid haemorrhage	False	- Empty -	12/18/2018 10:04:02 AM CT	tmsystem	TBRole	001-Mathew	
Subarachnoid haemorrhage	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
MedDRA PT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10042316	False	- Empty -	11/20/2018 7:02:00 AM CT	tmsystem	TBRole	001-Mathew	
10042316	False	- Empty -	12/18/2018 10:04:02 AM CT	tmsystem	TBRole	001-Mathew	
10042316	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Cerebral injuries NEC	False	- Empty -	11/20/2018 7:02:00 AM CT	tmsystem	TBRole	001-Mathew	
Cerebral injuries NEC	False	- Empty -	12/18/2018 10:04:02 AM CT	tmsystem	TBRole	001-Mathew	
Cerebral injuries NEC	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10052638	False	- Empty -	11/20/2018 7:02:00 AM CT	tmsystem	TBRole	001-Mathew	
10052638	False	- Empty -	12/18/2018 10:04:02 AM CT	tmsystem	TBRole	001-Mathew	
10052638	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLGT Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Injuries NEC	False	- Empty -	11/20/2018 7:02:00 AM CT	tmsystem	TBRole	001-Mathew	
Injuries NEC	False	- Empty -	12/18/2018 10:04:02 AM CT	tmsystem	TBRole	001-Mathew	
Injuries NEC	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
MedDRA HLGT Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10022114	False	- Empty -	11/20/2018 7:02:00 AM CT	tmsystem	TBRole	001-Mathew	
10022114	False	- Empty -	12/18/2018 10:04:02 AM CT	tmsystem	TBRole	001-Mathew	
10022114	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
MedDRA SOC Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Injury, poisoning and procedural complications	False	- Empty -	11/20/2018 7:02:00 AM CT	tmsystem	TBRole	001-Mathew	
Injury, poisoning and procedural complications	False	- Empty -	12/18/2018 10:04:02 AM CT	tmsystem	TBRole	001-Mathew	
Injury, poisoning and procedural complications	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
MedDRA SOC Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
10022117	False	- Empty -	11/20/2018 7:02:00 AM CT	tmsystem	TBRole	001-Mathew	
10022117	False	- Empty -	12/18/2018 10:04:02 AM CT	tmsystem	TBRole	001-Mathew	
10022117	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for New SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	12/17/2018 2:24:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Concatenated field used for Updated SAE Notification.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE_2018/09/15_SEVERE_CONTINUOUS_RESOLVED_	False	- Empty -	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE_2018/09/15_SEVERE_CONTINUOUS_Y_RESOLVED_	False	- Empty -	12/17/2018 2:24:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE_2018/09/15_SEVERE_CONTINUOUS_Y_RESOLVED_NOT RELATED	False	- Empty -	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE_2018/09/15_SEVERE_CONTINUOUS_Y_RESOLVED_NOT RELATED	True	- Empty -	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew	
Not a true data. Flag is used for SAE comparison.							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty	11/19/2018 10:58:35 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
SUBARACHNOID HEMORRHAGE_2018/09/15_SEVERE_CONTINUOUS_RESOLVED_	False	- Empty	11/19/2018 11:09:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
SUBARACHNOID HEMORRHAGE_2018/09/15_SEVERE_CONTINUOUS_Y_RESOLVED_	False	- Empty	12/17/2018 2:24:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
SUBARACHNOID HEMORRHAGE_2018/09/15_SEVERE_CONTINUOUS_Y_RESOLVED_NOT RELATED	False	- Empty	1/2/2019 12:55:43 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
SUBARACHNOID HEMORRHAGE_2018/09/15_SEVERE_CONTINUOUS_Y_RESOLVED_NOT RELATED	True	- Empty	2/12/2019 6:24:44 AM CT	(b) (6)	CRA	001-Mathew

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN **Visit Name:** iCRF **Status:** Signed Locked
Subject Caption: 001023 **Visit Date:** **Subject Initials:**
Subject Number: 001023 **Current Time:**

Concomitant Medications

Were any medications taken? ☒ No ☒ Yes

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	9/28/2018 10:38:08 AM CT	(b) (6)	CRA	001-Mathew
Complete	11/19/2018 11:10:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/4/2018 7:44:16 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/13/2019 12:35:01 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/13/2019 2:16:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/13/2019 2:31:49 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Form: Concomitant Medications							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please enter the conmeds taken due to the SAE once medical records are received and entered into ClinQuick.	9/28/2018 10:38:08 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	N/A	ENTERED	11/19/2018 11:10:15 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	N/A	Updated.	12/4/2018 7:44:16 PM CT	(b) (6)	CRA	001-Mathew	
Group: CMYN							
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	N/A	Please add the Fentanyl per the conmed source and medical records and update the start and stop date to 15-Sep-2018 per the medical records in the source and CRF.	2/13/2019 12:35:01 PM CT	(b) (6)	CRA	001-Mathew	

- Empty -	N/A	updated	2/13/2019 2:16:04 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	N/A	Added.	2/13/2019 2:31:49 PM CT	(b) (6)	CRA	001- Mathew	
Were any medications taken?							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/23/2018 9:51:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
Y	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
Y	True	- Empty -	12/4/2018 7:44:16 PM CT	(b) (6)	CRA	001- Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-ACETAMINOPHEN

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	1
Medication / Therapy Name	ACETAMINOPHEN
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	1-TEMPORAL HEADACHE
Dose	500
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Once
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Start Date	16/AUG/2018 DD/MON/YYYY(EN)
Start Time	16:49 HH:MM
Ongoing	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
End Date	16/AUG/2018 DD/MON/YYYY(EN)
End Time	16:49 HH:MM

Verbatim Term	ACETAMINOPHEN
Trade Name	ACETAMINOPHEN
Generic Name	ACETAMINOPHEN
Level 1 Code	N
Level 1 Term	NERVOUS SYSTEM
Level 2 Code	N02
Level 2 Term	ANALGESICS
Level 3 Code	N02B
Level 3 Term	OTHER ANALGESICS AND ANTIPYRETICS
Level 4 Code	N02BE
Level 4 Term	ANILIDES

Drug Record Number	000200	+
WHODrug SEQ1	01	+
WHODrug SEQ2	009	+
Route for Coding	Oral	≡
Indication for Coding	TEMPORAL HEADACHE	≡
Country for Coding	UNITED STATES	≡

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 3:51:30 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/7/2019 6:00:23 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ACETAMINOPHEN	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ACETAMINOPHEN	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Indication							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1-TEMPORAL HEADACHE	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1-TEMPORAL HEADACHE	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
500	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
500	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONCE	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONCE	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:49	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:49	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:49	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16:49	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:52:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
ACETAMINOPHEN	False	Question value " updated to 'ACETAMINOPHEN' by VTS based on DataChange editId 9874.	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/25/2019 2:38:01 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/25/2019 2:38:01 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew	
N	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew	
NERVOUS SYSTEM	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew	
N02	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	

Level 2 Term								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew		
- Empty -	False	- Empty -	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew		
ANALGESICS	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew		
Level 3 Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew		
- Empty -	False	- Empty -	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew		
N02B	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew		
Level 3 Term								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew		
- Empty -	False	- Empty -	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew		
OTHER ANALGESICS AND ANTIPYRETICS	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew		
Level 4 Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew		
N02BE	True	- Empty -	2/25/2019 2:38:01 PM CT	tmsystem	TBRole	001-Mathew		
Level 4 Term								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew		

ANILIDES	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew	
000200	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:00 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:00 PM CT	(b) (6)	CRA	001-Mathew	
009	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 907.	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew	
Oral	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE	False	Question value " updated to 'TEMPORAL HEADACHE' by VTS based on DataChange editId 904.	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew	

TEMPORAL HEADACHE	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:51:08 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 908.	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	12/4/2018 7:43:05 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-ACETAMINOPHEN

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	2
Medication / Therapy Name	ACETAMINOPHEN
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	1-TEMPORAL HEADACHE
Dose	500
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Once
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Start Date	16/AUG/2018 DD/MON/YYYY(EN)
Start Time	23:51 HH:MM
Ongoing	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes
End Date	16/AUG/2018 DD/MON/YYYY(EN)
End Time	23:51 HH:MM

Verbatim Term	ACETAMINOPHEN
Trade Name	ACETAMINOPHEN
Generic Name	ACETAMINOPHEN
Level 1 Code	N
Level 1 Term	NERVOUS SYSTEM
Level 2 Code	N02
Level 2 Term	ANALGESICS
Level 3 Code	N02B
Level 3 Term	OTHER ANALGESICS AND ANTIPYRETICS
Level 4 Code	N02BE
Level 4 Term	ANILIDES

Drug Record Number	000200	+
WHODrug SEQ1	01	+
WHODrug SEQ2	009	+
Route for Coding	Oral	≡
Indication for Coding	TEMPORAL HEADACHE	≡
Country for Coding	UNITED STATES	≡

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 3:51:30 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/7/2019 6:00:27 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
2	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ACETAMINOPHEN	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ACETAMINOPHEN	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Indication							1
	Field						

Response	Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1-TEMPORAL HEADACHE	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1-TEMPORAL HEADACHE	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
500	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
500	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONCE	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONCE	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
23:51	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
23:51	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
16/AUG/2018	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
23:51	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
23:51	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/24/2018 3:53:19 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
ACETAMINOPHEN	False	Question value " updated to 'ACETAMINOPHEN' by VTS based on DataChange editId 9874.	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew	
N	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew	
NERVOUS SYSTEM	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew	
N02	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	

Level 2 Term								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew		
- Empty -	False	- Empty -	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew		
ANALGESICS	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew		
Level 3 Code								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew		
- Empty -	False	- Empty -	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew		
N02B	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew		
Level 3 Term								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew		
- Empty -	False	- Empty -	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew		
OTHER ANALGESICS AND ANTIPYRETICS	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew		
Level 4 Code								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew		
N02BE	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew		
Level 4 Term								1
Response	Field Moni tored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew		

ANILIDES	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew	
000200	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:45:10 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:05 PM CT	(b) (6)	CRA	001-Mathew	
009	True	- Empty -	2/25/2019 2:38:02 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 907.	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew	
Oral	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TEMPORAL HEADACHE	False	Question value " updated to 'TEMPORAL HEADACHE' by VTS based on DataChange editId 904.	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew	

TEMPORAL HEADACHE	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	8/24/2018 3:52:27 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 908.	8/28/2018 5:15:54 PM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	12/4/2018 7:43:23 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-OXYCODONE

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	3
Medication / Therapy Name	OXYCODONE
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	4-SUBARACHNOID HEMORRHAGE
Dose	5
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Other
If Other Frequency, specify	Every 4 hours
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="radio"/> No <input type="radio"/> Yes
Start Date	<input checked="" type="radio"/> 02/OCT/2018 DD/MON/YYYY(EN)
Start Time	UNK:UNK HH:MM
Ongoing	<input checked="" type="radio"/> <input type="radio"/> No <input type="radio"/> Yes
End Date	<input checked="" type="radio"/>
End Time	<input checked="" type="radio"/>
Verbatim Term	OXYCODONE
Trade Name	OXYCODONE
Generic Name	OXYCODONE
Level 1 Code	N
Level 1 Term	NERVOUS SYSTEM
Level 2 Code	N02
Level 2 Term	ANALGESICS
Level 3 Code	N02A
Level 3 Term	OPIOIDS
Level 4 Code	N02AA
Level 4 Term	NATURAL OPIUM ALKALOIDS

Drug Record Number	000456	+
WHODrug SEQ1	01	+
WHODrug SEQ2	001	+
Route for Coding	Oral	≡
Indication for Coding	SUBARACHNOID HEMORRHAGE	≡
Country for Coding	UNITED STATES	≡

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:12:57 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	11/19/2018 11:14:41 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:15:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	12/13/2018 7:41:52 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Complete	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	12/19/2018 4:12:22 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew
Partial Monitored	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	1/10/2019 4:01:00 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/6/2019 5:18:58 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew
Partial Monitored	2/7/2019 6:01:08 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 10:51:11 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 10:55:45 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/13/2019 8:27:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Partial Monitored	2/13/2019 12:28:44 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/13/2019 12:32:21 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/13/2019 12:50:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/13/2019 1:03:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/13/2019 1:04:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/13/2019 1:04:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/13/2019 1:06:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/13/2019 1:15:30 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History	
Question Audit History	
Concomitant Medication Number	1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
3	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	

Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OXYCODONE	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OXYCODONE	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	

Indication							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	

If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	

Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

TABLET	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRN	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
PRN	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
PRN	False	Please change to Q4H per the medical records in the conmed report and CRF.	2/13/2019 12:32:21 PM CT	(b) (6)	CRA	001-Mathew	
OTHER	False	Transcription Error	2/13/2019 1:03:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	False	updated	2/13/2019 1:03:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	False	updated	2/13/2019 1:04:53 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	True	Updated.	2/13/2019 1:15:30 PM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
Q4H	False	Transcription Error	2/13/2019 1:03:09 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Q4H	True	- Empty -	2/13/2019 1:15:30 PM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	

Was the medication/therapy taken prior to the study? 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	

Start Date 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	(Start Date should be prior to or equal to the Date of Completion or Discontinuation.) correct as is	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	True	Correct as entered.	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	

Start Time 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	

Ongoing 1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	(This item is required.) END DATE AND TIME ARE UNKNOWN	11/19/2018 11:15:13 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	If event ended, please update 'Ongoing' to 'No', and provide answers to the end date and end time as available. Probe for year if possible.	12/13/2018 7:41:52 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	- Empty -	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Please see the response of DM to other query.	1/10/2019 4:01:00 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	Issuing query from DM directly.	2/6/2019 5:18:58 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	If event ended, please update 'Ongoing' to 'No', and provide answers to the end date and end time as available. Probe for year if possible.	2/6/2019 5:18:58 PM CT	(b) (6)	CRA	001-Mathew	
N	False	UPDATED	2/13/2019 8:27:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Transcription Error	2/13/2019 8:27:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Closed automatically	2/13/2019 8:27:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	Will re-issue query.	2/13/2019 12:28:44 PM CT	(b) (6)	CRA	001-Mathew	
N	False	Please change to blank as this was unknown.	2/13/2019 12:28:44 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	updated	2/13/2019 12:50:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Transcription Error	2/13/2019 12:50:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(Query reopened due to data change): Transcription Error	2/13/2019 12:50:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	updated	2/13/2019 1:04:22 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	updated	2/13/2019 1:06:32 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Updated.	2/13/2019 1:15:30 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	Updated.	2/13/2019 1:15:30 PM CT	(b) (6)	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Can you probe subject for year? e.g. UNK/UNK/2017	12/13/2018 7:41:52 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	subject is lost to follow up	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Update made. Query closed.	12/19/2018 4:12:22 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	(This item is required.) STOP DATE IS UNKNOWN, SUBJECT LOST TO FOLLOW UP	2/13/2019 8:27:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Unknown per source.	2/13/2019 12:28:44 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 12:50:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:12:55 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Update to UNK:UNK if time unavailable and event is not ongoing.	12/13/2018 7:41:52 AM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	False	subject is lost to follow up	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Update made. Query closed.	12/19/2018 4:12:22 PM CT	(b) (6)	Clinical Data Manager (CDM)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	(This item is required.) STOP TIME IS UNKNOWN, SUBJECT LOST TO FOLLOW UP	2/13/2019 8:27:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Unknown per source.	2/13/2019 12:28:44 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 12:50:57 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/17/2018 1:27:33 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
OXYCODONE	False	Question value " updated to 'OXYCODONE' by VTS based on DataChange editId 9874.	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
OXYCODONE	True	- Empty -	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
OXYCODONE	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
OXYCODONE	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew	
N	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew	
NERVOUS SYSTEM	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew	
N02	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew	
ANALGESICS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew	
N02A	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew	
OPIOIDS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
N02AA	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
NATURAL OPIUM ALKALOIDS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew	
000456	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:22 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:47 PM CT	(b) (6)	CRA	001-Mathew	
001	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 2443.	11/19/2018 11:12:57 AM CT	(b) (6)	Setup Administrator	001-Mathew	
Oral	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 2442.	11/19/2018 11:12:57 AM CT	(b) (6)	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:10:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 11:12:57 AM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	1/10/2019 3:41:17 PM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-NIMODIPINE

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	4
Medication / Therapy Name	NIMODIPINE
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	4-SUBARACHNOID HEMORRHAGE
Dose	60
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Other
If Other Frequency, specify	Every 4 hours
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="radio"/> No <input type="radio"/> Yes
Start Date	<input checked="" type="checkbox"/> 02/OCT/2018 DD/MON/YYYY(EN)
Start Time	UNK:UNK HH:MM
Ongoing	<input checked="" type="checkbox"/> <input type="radio"/> No <input type="radio"/> Yes
End Date	
End Time	

Verbatim Term	NIMODIPINE
Trade Name	NIMODIPINE
Generic Name	NIMODIPINE
Level 1 Code	C
Level 1 Term	CARDIOVASCULAR SYSTEM
Level 2 Code	C08
Level 2 Term	CALCIUM CHANNEL BLOCKERS
Level 3 Code	C08C
Level 3 Term	SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS
Level 4 Code	C08CA

Level 4 Term	DIHYDROPYRIDINE DERIVATIVES	+
Drug Record Number	009184	+
WHODrug SEQ1	01	+
WHODrug SEQ2	001	+
Route for Coding	Oral	≡
Indication for Coding	SUBARACHNOID HEMORRHAGE	≡
Country for Coding	UNITED STATES	≡

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:17:32 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	12/4/2018 8:43:03 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/5/2018 7:16:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/7/2019 6:00:42 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/13/2019 12:33:35 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/13/2019 1:03:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/13/2019 1:14:18 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NIMODIPINE	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
NIMODIPINE	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	

Indication							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	

If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:16:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	

Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:16:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	

Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	

Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
30	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
30	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
30	False	Please change to 60 mg per the medical records in the source and CRF.	2/13/2019 12:33:35 PM CT	(b) (6)	CRA	001-Mathew	
60	False	Transcription Error	2/13/2019 1:03:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
60	False	updated	2/13/2019 1:03:41 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
60	True	Updated.	2/13/2019 1:14:18 PM CT	(b) (6)	CRA	001-Mathew	

Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	

If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:16:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	

Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	

Frequency							1
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Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Q4H	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Q4H	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:16:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	

Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	(Start Date should be prior to or equal to the Date of Completion or Discontinuation.) correct as is	12/5/2018 7:16:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	True	Correct as entered.	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) END DATE AND TIME ARE UNKNOWN	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Unknown per source.	12/4/2018 8:43:03 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	Please by-pass entry.	12/4/2018 8:43:03 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	updated	12/5/2018 7:16:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Completed.	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:16:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:17:30 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:16:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:16:27 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
NIMODIPINE	False	Question value " updated to 'NIMODIPINE' by VTS based on DataChange editId 9874.	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
NIMODIPINE	True	- Empty -	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
NIMODIPINE	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
NIMODIPINE	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew	
C	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew	
CARDIOVASCULAR SYSTEM	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew	
C08	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew	
CALCIUM CHANNEL BLOCKERS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew	
C08C	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew	
SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
C08CA	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
DIHYDROPYRIDINE DERIVATIVES	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew	
009184	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	

WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:36 PM CT	(b) (6)	CRA	001-Mathew	
001	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 2443.	11/19/2018 11:17:32 AM CT	(b) (6)	Setup Administrator	001-Mathew	
Oral	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 2442.	11/19/2018 11:17:32 AM CT	(b) (6)	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:15:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 11:17:32 AM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	12/5/2018 10:59:11 AM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-ONDANSETRON

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	5
Medication / Therapy Name	ONDANSETRON
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	4-SUBARACHNOID HEMORRHAGE
Dose	4
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Other
If Other Frequency, specify	Every 6 hours
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="radio"/> No <input type="radio"/> Yes
Start Date	<input checked="" type="checkbox"/> 02/OCT/2018 DD/MON/YYYY(EN)
Start Time	UNK:UNK HH:MM
Ongoing	<input checked="" type="checkbox"/> <input type="radio"/> No <input type="radio"/> Yes
End Date	
End Time	
Verbatim Term	ONDANSETRON
Trade Name	ONDANSETRON
Generic Name	ONDANSETRON
Level 1 Code	A
Level 1 Term	ALIMENTARY TRACT AND METABOLISM
Level 2 Code	A04
Level 2 Term	ANTIEMETICS AND ANTINAUSEANTS
Level 3 Code	A04A
Level 3 Term	ANTIEMETICS AND ANTINAUSEANTS
Level 4 Code	A04AA
Level 4 Term	SEROTONIN (5HT3) ANTAGONISTS

Drug Record Number	009553	+
WHODrug SEQ1	01	+
WHODrug SEQ2	001	+
Route for Coding	Oral	≡
Indication for Coding	SUBARACHNOID HEMORRHAGE	≡
Country for Coding	UNITED STATES	≡

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:19:12 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	12/4/2018 8:43:41 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/5/2018 7:15:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/7/2019 6:00:45 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
5	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONDANSETRON	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ONDANSETRON	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	

Indication								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
ADVERSE EVENT	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
ADVERSE EVENT	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew		

If Other Indication, specify								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	12/5/2018 7:15:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew		

Primary Medical History Term								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	12/5/2018 7:15:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew		

Primary Adverse Event Term								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
4-SUBARACHNOID HEMORRHAGE	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew		

Dose								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew		

4	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:15:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Q6H	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Q6H	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:15:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	(Start Date should be prior to or equal to the Date of Completion or Discontinuation.) correct as is	12/5/2018 7:15:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

02/OCT/2018	True	Correct as entered.	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001- Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
UNK:UNK	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
UNK:UNK	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001- Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	(This item is required.) END DATE AND TIME ARE UNKNOWN	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	Unknown per source.	12/4/2018 8:43:41 PM CT	(b) (6)	CRA	001- Mathew	
- Empty -	False	Please by-pass entry.	12/4/2018 8:43:41 PM CT	(b) (6)	CRA	001- Mathew	
- Empty -	False	updated	12/5/2018 7:15:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	Completed.	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001- Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	12/5/2018 7:15:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001- Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	11/19/2018 11:19:09 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	12/5/2018 7:15:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	

- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:15:45 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
ONDANSETRON	False	Question value " updated to 'ONDANSETRON' by VTS based on DataChange editId 9874.	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ONDANSETRON	True	- Empty -	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ONDANSETRON	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ONDANSETRON	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew	
A	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew	
ALIMENTARY TRACT AND METABOLISM	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew	
A04	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew	
ANTIEMETICS AND ANTINAUSEANTS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew	
A04A	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew	
ANTIEMETICS AND ANTINAUSEANTS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
A04AA	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
SEROTONIN (5HT3) ANTAGONISTS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew	
009553	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:42 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:41 PM CT	(b) (6)	CRA	001-Mathew	
001	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 2443.	11/19/2018 11:19:12 AM CT	(b) (6)	Setup Administrator	001-Mathew	
Oral	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 2442.	11/19/2018 11:19:12 AM CT	(b) (6)	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:17:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 11:19:12 AM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	12/5/2018 10:59:48 AM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-GABAPENTIN

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	6
Medication / Therapy Name	GABAPENTIN
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	4-SUBARACHNOID HEMORRHAGE
Dose	100
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Twice per day (BID)
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="radio"/> No <input type="radio"/> Yes
Start Date	<input checked="" type="checkbox"/> 02/OCT/2018 DD/MON/YYYY(EN)
Start Time	UNK:UNK HH:MM
Ongoing	<input checked="" type="checkbox"/> <input type="radio"/> No <input type="radio"/> Yes
End Date	
End Time	

Verbatim Term	GABAPENTIN
Trade Name	GABAPENTIN
Generic Name	GABAPENTIN
Level 1 Code	N
Level 1 Term	NERVOUS SYSTEM
Level 2 Code	N02
Level 2 Term	ANALGESICS
Level 3 Code	N02B
Level 3 Term	OTHER ANALGESICS AND ANTIPYRETICS
Level 4 Code	N02BG
Level 4 Term	OTHER ANALGESICS AND ANTIPYRETICS
Drug Record Number	010030

WHODrug SEQ1	01	
WHODrug SEQ2	001	
Route for Coding	Oral	
Indication for Coding	SUBARACHNOID HEMORRHAGE	
Country for Coding	UNITED STATES	

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:20:37 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	12/4/2018 8:41:54 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/7/2019 6:00:50 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
6	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
6	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GABAPENTIN	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
GABAPENTIN	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Indication							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
100	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

100	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BID	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
BID	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	(Start Date should be prior to or equal to the Date of Completion or Discontinuation.) updated	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

02/OCT/2018	True	Correct as entered.	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001- Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
UNK:UNK	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
UNK:UNK	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001- Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	(This item is required.) END DATE AND TIME ARE UNKNOWN	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	Unknown per source.	12/4/2018 8:41:54 PM CT	(b) (6)	CRA	001- Mathew	
- Empty -	False	Please by-pass entry.	12/4/2018 8:41:54 PM CT	(b) (6)	CRA	001- Mathew	
- Empty -	False	updated	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	Completed.	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001- Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001- Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	11/19/2018 11:20:32 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	

- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:20:26 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
GABAPENTIN	False	Question value " updated to 'GABAPENTIN' by VTS based on DataChange editId 9874.	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
GABAPENTIN	True	- Empty -	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
GABAPENTIN	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
GABAPENTIN	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew	
N	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew	
NERVOUS SYSTEM	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew	
N02	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew	
ANALGESICS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew	
N02B	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew	
OTHER ANALGESICS AND ANTIPYRETICS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
N02BG	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:31 PM CT	(b) (6)	Setup Administrator	001-Mathew	
OTHER ANALGESICS AND ANTIPYRETICS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew	
010030	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:53:52 PM CT	(b) (6)	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	2/24/2019 11:48:32 PM CT	(b) (6)	CRA	001-Mathew	
001	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 2443.	11/19/2018 11:20:37 AM CT	(b) (6)	Setup Administrator	001-Mathew	
Oral	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 2442.	11/19/2018 11:20:37 AM CT	(b) (6)	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:19:18 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 11:20:37 AM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	12/5/2018 10:58:34 AM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-DOCUSATE SODIUM

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	7
Medication / Therapy Name	DOCUSATE SODIUM
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	4-SUBARACHNOID HEMORRHAGE
Dose	100
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Daily (QD)
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="radio"/> No <input type="radio"/> Yes
Start Date	<input checked="" type="checkbox"/> 02/OCT/2018 DD/MON/YYYY(EN)
Start Time	UNK:UNK HH:MM
Ongoing	<input checked="" type="checkbox"/> <input type="radio"/> No <input type="radio"/> Yes
End Date	
End Time	

Verbatim Term	DOCUSATE SODIUM
Trade Name	DOCUSATE SODIUM
Generic Name	DOCUSATE SODIUM
Level 1 Code	A
Level 1 Term	ALIMENTARY TRACT AND METABOLISM
Level 2 Code	A06
Level 2 Term	DRUGS FOR CONSTIPATION
Level 3 Code	A06A
Level 3 Term	DRUGS FOR CONSTIPATION
Level 4 Code	A06AA
Level 4 Term	SOFTENERS, EMOLLIENTS
Drug Record Number	000616

WHODrug SEQ1	02	+
WHODrug SEQ2	001	+
Route for Coding	Oral	≡
Indication for Coding	SUBARACHNOID HEMORRHAGE	≡
Country for Coding	UNITED STATES	≡

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:21:52 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	12/4/2018 8:41:05 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 3:51:32 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/7/2019 6:00:53 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
7	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
7	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOCUSATE SODIUM	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DOCUSATE SODIUM	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Indication							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
100	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

100	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QD	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
QD	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	(Start Date should be prior to or equal to the Date of Completion or Discontinuation.) correct as is	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

02/OCT/2018	True	Correct as entered.	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001- Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
UNK:UNK	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
UNK:UNK	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001- Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	(This item is required.) END DATE AND TIME ARE UNKNOWN	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	Unknown per source.	12/4/2018 8:41:05 PM CT	(b) (6)	CRA	001- Mathew	
- Empty -	False	Please by-pass.	12/4/2018 8:41:05 PM CT	(b) (6)	CRA	001- Mathew	
- Empty -	False	updated	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	Completed.	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001- Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001- Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	11/19/2018 11:21:51 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	
- Empty -	False	- Empty -	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001- Mathew	

- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:21:03 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
DOCUSATE SODIUM	False	Question value " updated to 'DOCUSATE SODIUM' by VTS based on DataChange editId 9874.	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
DOCUSATE SODIUM	True	- Empty -	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
DOCUSATE SODIUM	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
DOCUSATE SODIUM	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew	
A	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew	
ALIMENTARY TRACT AND METABOLISM	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew	
A06	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew	
DRUGS FOR CONSTIPATION	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew	
A06A	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew	
DRUGS FOR CONSTIPATION	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
A06AA	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
SOFTENERS, EMOLLIENTS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew	
000616	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew	
02	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:02 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:23 PM CT	(b) (6)	CRA	001-Mathew	
001	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 2443.	11/19/2018 11:21:52 AM CT	(b) (6)	Setup Administrator	001-Mathew	
Oral	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 2442.	11/19/2018 11:21:52 AM CT	(b) (6)	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:20:40 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 11:21:52 AM CT	(b) (6)	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	12/5/2018 10:57:50 AM CT	(b) (6)	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-ACETAMINOPHEN

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	8	
Medication / Therapy Name	ACETAMINOPHEN	
Indication	Adverse Event	
Primary Medical History Term		
Primary Adverse Event Term	4-SUBARACHNOID HEMORRHAGE	
Dose	1000	
Unit	Milligram	
Dose Form	Tablet; tab	
Frequency	Other	
If Other Frequency, specify	Every 6 hours	
Route	Oral	
Was the medication/therapy taken prior to the study?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
Start Date	<div>B 02/OCT/2018</div> <div>DD/MON/YYYY(EN)</div>	
Start Time	UNK:UNK HH:MM	
Ongoing	<div>B <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes</div>	
End Date		
End Time		
Verbatim Term	ACETAMINOPHEN	
Trade Name	ACETAMINOPHEN	
Generic Name	ACETAMINOPHEN	
Level 1 Code	N	
Level 1 Term	NERVOUS SYSTEM	
Level 2 Code	N02	
Level 2 Term	ANALGESICS	
Level 3 Code	N02B	
Level 3 Term	OTHER ANALGESICS AND ANTIPYRETICS	
Level 4 Code	N02BE	
Level 4 Term	ANILIDES	

Drug Record Number	000200	
WHODrug SEQ1	01	
WHODrug SEQ2	009	
Route for Coding	Oral	
Indication for Coding	SUBARACHNOID HEMORRHAGE	
Country for Coding	UNITED STATES	

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	11/19/2018 11:23:17 AM CT	(b) (6)	Setup Administrator	001-Mathew
Incomplete	12/4/2018 8:40:12 PM CT	(b) (6)	CRA	001-Mathew
Incomplete	12/4/2018 8:40:22 PM CT	(b) (6)	CRA	001-Mathew
Complete	12/5/2018 7:19:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/7/2019 3:51:32 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/7/2019 6:00:59 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/13/2019 12:32:52 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/13/2019 1:05:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/13/2019 1:15:52 PM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:54:12 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:13 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
8	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
8	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ACETAMINOPHEN	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ACETAMINOPHEN	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Indication							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:19:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:19:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Dose							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
500	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
500	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
500	False	Please change to 1000 mg per the medical records in the source and CRF.	2/13/2019 12:32:52 PM CT	(b) (6)	CRA	001-Mathew	
1000	False	Transcription Error	2/13/2019 1:05:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1000	False	updated	2/13/2019 1:05:24 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
1000	True	Updated.	2/13/2019 1:15:52 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:19:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Q6H	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Q6H	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:19:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Start Date							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	False	(Start Date should be prior to or equal to the Date of Completion or Discontinuation.) correct as is	12/5/2018 7:19:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
02/OCT/2018	True	Correct as entered.	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) END DATE AND TIME ARE UNKNOWN	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	Unknown per the source.	12/4/2018 8:40:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	Please by-pass this entry.	12/4/2018 8:40:12 PM CT	(b) (6)	CRA	001-Mathew	
- Empty -	False	updated	12/5/2018 7:19:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Completed.	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:19:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	11/19/2018 11:23:16 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:19:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	12/5/2018 7:19:49 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
ACETAMINOPHEN	False	Question value " updated to 'ACETAMINOPHEN' by VTS based on DataChange editId 9874.	2/22/2019 6:54:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/24/2019 11:48:13 PM CT	(b) (6)	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
	Field						

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ACETAMINOPHEN	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:13 PM CT	(b) (6)	CRA	001-Mathew	
N	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:13 PM CT	(b) (6)	CRA	001-Mathew	
NERVOUS SYSTEM	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:13 PM CT	(b) (6)	CRA	001-Mathew	
N02	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:13 PM CT	(b) (6)	CRA	001-Mathew	
ANALGESICS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6)	prod	TBMigration	001-Mathew
- Empty -	False	- Empty -	2/22/2019 6:54:12 PM CT	(b) (6)		Setup Administrator	001-Mathew
- Empty -	True	- Empty -	2/24/2019 11:48:13 PM CT	(b) (6)		CRA	001-Mathew
N02B	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem		TBRole	001-Mathew
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6)	prod	TBMigration	001-Mathew
- Empty -	False	- Empty -	2/22/2019 6:54:12 PM CT	(b) (6)		Setup Administrator	001-Mathew
- Empty -	True	- Empty -	2/24/2019 11:48:13 PM CT	(b) (6)		CRA	001-Mathew
OTHER ANALGESICS AND ANTIPYRETICS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem		TBRole	001-Mathew
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
N02BE	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
- Empty -	True	- Empty -	2/7/2019 3:51:32 PM CT	(b) (6)	Setup Administrator	001-Mathew	
ANILIDES	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6)	prod	TBMigration	001-Mathew
- Empty -	False	- Empty -	2/22/2019 6:54:12 PM CT	(b) (6)		Setup Administrator	001-Mathew
- Empty -	True	- Empty -	2/24/2019 11:48:13 PM CT	(b) (6)		CRA	001-Mathew
000200	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem		TBRole	001-Mathew
WHODrug SEQ1							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:13 PM CT	(b) (6)	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	(b) (6) prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:12 PM CT	(b) (6)	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:13 PM CT	(b) (6)	CRA	001-Mathew	
009	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 2443.	11/19/2018 11:23:17 AM CT	(b) (6)	Setup Administrator	001-Mathew	
Oral	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 2442.	11/19/2018 11:23:17 AM CT	(b) (6)	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	11/19/2018 11:22:00 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 2446.	11/19/2018 11:23:17 AM CT	(b) (6)	Setup Administrator	001-Mathew	

UNITED STATES	True	- Empty -	12/5/2018 10:56:58 AM CT	(b) (6)	CRA	001-Mathew
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iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	(b) (6)	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	(b) (6)	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	(b) (6)	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	(b) (6) prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	(b) (6) prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	(b) (6) prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	(b) (6) prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-FENTANYL

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	9
Medication / Therapy Name	FENTANYL
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	4-SUBARACHNOID HEMORRHAGE
Dose	50
Unit	Microgram
Dose Form	Drug Delivery System
Frequency	Other
If Other Frequency, specify	Continuous
Route	Intravenous
Was the medication/therapy taken prior to the study?	<input checked="" type="radio"/> No <input type="radio"/> Yes
Start Date	<input checked="" type="radio"/> 15/SEP/2018 DD/MON/YYYY(EN)
Start Time	<input checked="" type="radio"/> UNK:UNK HH:MM
Ongoing	<input checked="" type="radio"/> No <input type="radio"/> Yes
End Date	<input checked="" type="radio"/> 15/SEP/2018 DD/MON/YYYY(EN)
End Time	<input checked="" type="radio"/> UNK:UNK HH:MM

Verbatim Term	FENTANYL
Trade Name	FENTANYL
Generic Name	FENTANYL
Level 1 Code	N
Level 1 Term	NERVOUS SYSTEM
Level 2 Code	N02
Level 2 Term	ANALGESICS
Level 3 Code	N02A
Level 3 Term	OPIOIDS

Level 4 Code	N02AB	+
Level 4 Term	PHENYLPIPERIDINE DERIVATIVES	+
Drug Record Number	001746	+
WHODrug SEQ1	01	+
WHODrug SEQ2	001	+
Route for Coding	Intravenous	≡
Indication for Coding	SUBARACHNOID HEMORRHAGE	≡
Country for Coding	UNITED STATES	≡

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/13/2019 2:20:10 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew
Complete	2/14/2019 8:42:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/14/2019 8:48:20 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/14/2019 9:12:53 AM CT	(b) (6)	CRA	001-Mathew
Partial Monitored	2/22/2019 6:54:22 PM CT	(b) (6)	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:27 PM CT	(b) (6)	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	(b) (6)	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	(b) (6)	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
9	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
9	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
FENTANYL	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

FENTANYL	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Indication							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
50	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	

50	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ug	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
ug	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SOLUTION	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
SOLUTION	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
DRUG DELIVERY SYSTEM	False	Transcription Error	2/14/2019 8:42:25 AM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
DRUG DELIVERY SYSTEM	True	- Empty -	2/14/2019 9:12:53 AM CT	(b) (6)	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
OTHER	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
CONTINUOUS	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTRAVENOUS	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
INTRAVENOUS	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	False	(Start Date should be prior to or equal to the Date of Completion or Discontinuation.) CORRECT AS IS	2/13/2019 2:20:07 PM CT	(b) (6)	Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	True	Correct per source.	2/13/2019 2:32:51 PM CT	(b) (6)	CRA	001-Mathew	
Start Time							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) START TIME UNKNOWN	2/13/2019 2:20:07 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/13/2019 2:32:51 PM CT	stier	CRA	001-Mathew	
UNK:UNK	False	Transcription Error	2/14/2019 8:48:20 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	2/14/2019 9:12:53 AM CT		CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT		Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	2/13/2019 2:20:07 PM CT		Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/13/2019 2:32:51 PM CT		CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT		Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	False	(End date should be prior to or equal to the Date of Completion or Discontinuation.) CORRECT AS IS	2/13/2019 2:20:07 PM CT		Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	True	Correct per source.	2/13/2019 2:32:51 PM CT		CRA	001-Mathew	
15/SEP/2018	False	(End time should be equal or after start time.) CORRECT AS IS	2/14/2019 8:48:20 AM CT		Clinical Research Coordinator (CRC)	001-Mathew	
15/SEP/2018	True	Correct as entered.	2/14/2019 9:12:53 AM CT		CRA	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT		Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) STOP TIME UNKNOWN	2/13/2019 2:20:07 PM CT		Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct per source.	2/13/2019 2:32:51 PM CT		CRA	001-Mathew	
UNK:UNK	False	Transcription Error	2/14/2019 8:48:20 AM CT		Clinical Research Coordinator (CRC)	001-Mathew	

UNK:UNK	True	- Empty -	2/14/2019 9:12:53 AM CT	stier	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/13/2019 2:20:07 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 2:32:51 PM CT	stier	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
FENTANYL	False	Question value " updated to 'FENTANYL' by VTS based on DataChange editId 9874.	2/22/2019 6:54:22 PM CT	imvalidation	Setup Administrator	001-Mathew	
FENTANYL	True	- Empty -	2/24/2019 11:48:27 PM CT	stier	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/13/2019 2:20:10 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 2:32:51 PM CT	stier	CRA	001-Mathew	
FENTANYL	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/13/2019 2:20:10 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 2:32:51 PM CT	stier	CRA	001-Mathew	
FENTANYL	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:22 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:27 PM CT	istier	CRA	001-Mathew	
N	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:22 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:27 PM CT	istier	CRA	001-Mathew	
NERVOUS SYSTEM	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:22 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:27 PM CT	istier	CRA	001-Mathew	
N02	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:22 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:27 PM CT	istier	CRA	001-Mathew	
ANALGESICS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:22 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:27 PM CT	istier	CRA	001-Mathew	
N02A	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:22 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:27 PM CT	istier	CRA	001-Mathew	
OPIOIDS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	

Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/13/2019 2:20:10 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 2:32:51 PM CT	stier	CRA	001-Mathew	
N02AB	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/13/2019 2:20:10 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/13/2019 2:32:51 PM CT	stier	CRA	001-Mathew	
PHENYLPIPERIDINE DERIVATIVES	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:22 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:27 PM CT	stier	CRA	001-Mathew	
001746	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:22 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:27 PM CT	stier	CRA	001-Mathew	
01	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:22 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:27 PM CT	stier	CRA	001-Mathew	
001	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
Intravenous	False	Question value " updated to 'Intravenous' by VTS based on DataChange editId 7386.	2/13/2019 2:20:10 PM CT	invalidation	Setup Administrator	001-Mathew	
Intravenous	True	- Empty -	2/13/2019 2:32:51 PM CT	stier	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 7385.	2/13/2019 2:20:10 PM CT	invalidation	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	2/13/2019 2:32:51 PM CT	stier	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/13/2019 2:16:13 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 7388.	2/13/2019 2:20:10 PM CT	invalidation	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	2/13/2019 2:32:51 PM CT	stier	CRA	001-Mathew	

iCRF Version Change History				
Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	dbarber	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	skramer	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	ktrueman	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	gmedina prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	gmedina prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	gmedina prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	gmedina prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-PROTONIX

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	10
Medication / Therapy Name	PROTONIX
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	4-SUBARACHNOID HEMORRHAGE
Dose	20
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Daily (QD)
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="radio"/> No <input type="radio"/> Yes
Start Date	<input checked="" type="checkbox"/> 03/OCT/2018 DD/MON/YYYY(EN)
Start Time	UNK:UNK HH:MM
Ongoing	<input checked="" type="checkbox"/> <input type="radio"/> No <input type="radio"/> Yes
End Date	
End Time	

Verbatim Term	PROTONIX
Trade Name	PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE]
Generic Name	PANTOPRAZOLE SODIUM SESQUIHYDRATE
Level 1 Code	A
Level 1 Term	ALIMENTARY TRACT AND METABOLISM
Level 2 Code	A02
Level 2 Term	DRUGS FOR ACID RELATED DISORDERS
Level 3 Code	A02B
Level 3 Term	DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)
Level 4 Code	A02BC
Level 4 Term	PROTON PUMP INHIBITORS

Drug Record Number	012632	+
WHODrug SEQ1	04	+
WHODrug SEQ2	016	+
Route for Coding	Oral	≡
Indication for Coding	SUBARACHNOID HEMORRHAGE	≡
Country for Coding	UNITED STATES	≡

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew
Incomplete	2/14/2019 8:46:45 AM CT	imvalidation	Setup Administrator	001-Mathew
Complete	2/14/2019 8:49:22 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew
Monitored	2/14/2019 9:14:56 AM CT	istier	CRA	001-Mathew
Partial Monitored	2/22/2019 6:54:32 PM CT	imvalidation	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:49:03 PM CT	istier	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	alhunt	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	gmedina	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
10	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
10	True	- Empty -	2/14/2019 9:14:56 AM CT	istier	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
PROTONIX	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
PROTONIX	True	- Empty -	2/14/2019 9:14:56 AM CT	istier	CRA	001-Mathew	

Indication								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
ADVERSE EVENT	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
ADVERSE EVENT	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew		

If Other Indication, specify								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	2/14/2019 8:49:22 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew		

Primary Medical History Term								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	False	- Empty -	2/14/2019 8:49:22 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew		

Primary Adverse Event Term								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
4-SUBARACHNOID HEMORRHAGE	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew		

Dose								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		
20	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew		

20	True	- Empty -	2/14/2019 9:14:56 AM CT	tstier	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	2/14/2019 9:14:56 AM CT	tstier	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:49:22 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	tstier	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	2/14/2019 9:14:56 AM CT	tstier	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
QD	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
QD	True	- Empty -	2/14/2019 9:14:56 AM CT	tstier	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:49:22 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	istier	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	2/14/2019 9:14:56 AM CT	istier	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:49:22 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	istier	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/14/2019 9:14:56 AM CT	istier	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
03/OCT/2018	False	(Start Date should be prior to or equal to the Date of Completion or Discontinuation.) CORRECT AS IS	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
03/OCT/2018	True	Correct as entered.	2/14/2019 9:14:56 AM CT	istier	CRA	001-Mathew	
Start Time							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	2/14/2019 9:14:56 AM CT	tstier	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	(This item is required.) STOP DATE AND TIME ARE UNKNOWN	2/14/2019 8:49:22 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	Correct as entered.	2/14/2019 9:14:56 AM CT	tstier	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:49:22 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	tstier	CRA	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:46:45 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:49:22 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	tstier	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:49:22 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
PROTONIX	False	Question value " updated to 'PROTONIX' by VTS based on DataChange editId 9874.	2/22/2019 6:54:32 PM CT	imvalidation	Setup Administrator	001-Mathew	
PROTONIX	True	- Empty -	2/24/2019 11:49:03 PM CT	stier	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew	
- Empty -	True	- Empty -	2/22/2019 6:54:32 PM CT	imvalidation	Setup Administrator	001-Mathew	
PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE]	True	- Empty -	2/26/2019 5:41:00 AM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew	
- Empty -	True	- Empty -	2/22/2019 6:54:32 PM CT	imvalidation	Setup Administrator	001-Mathew	
PANTOPRAZOLE SODIUM SESQUIHYDRATE	True	- Empty -	2/26/2019 5:41:00 AM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:32 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:49:03 PM CT	stier	CRA	001-Mathew	
A	True	- Empty -	2/26/2019 5:41:00 AM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -		False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -		False	- Empty -	2/22/2019 6:54:32 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -		True	- Empty -	2/24/2019 11:49:03 PM CT	istier	CRA	001-Mathew	
ALIMENTARY TRACT AND METABOLISM		True	- Empty -	2/26/2019 5:41:00 AM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew		
- Empty -	False	- Empty -	2/22/2019 6:54:32 PM CT	imvalidation	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	2/24/2019 11:49:03 PM CT	istier	CRA	001-Mathew		
A02	True	- Empty -	2/26/2019 5:41:00 AM CT	tmsystem	TBRole	001-Mathew		
Level 2 Term								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew		
- Empty -	False	- Empty -	2/22/2019 6:54:32 PM CT	imvalidation	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	2/24/2019 11:49:03 PM CT	istier	CRA	001-Mathew		
DRUGS FOR ACID RELATED DISORDERS	True	- Empty -	2/26/2019 5:41:00 AM CT	tmsystem	TBRole	001-Mathew		
Level 3 Code								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew		
- Empty -	False	- Empty -	2/22/2019 6:54:32 PM CT	imvalidation	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	2/24/2019 11:49:03 PM CT	istier	CRA	001-Mathew		
A02B	True	- Empty -	2/26/2019 5:41:01 AM CT	tmsystem	TBRole	001-Mathew		
Level 3 Term								1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source	
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew		
- Empty -	False	- Empty -	2/22/2019 6:54:32 PM CT	imvalidation	Setup Administrator	001-Mathew		
- Empty -	True	- Empty -	2/24/2019 11:49:03 PM CT	istier	CRA	001-Mathew		

DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)			True	- Empty -	2/26/2019 5:41:01 AM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code									1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source		
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew			
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew			
- Empty -	True	- Empty -	2/22/2019 6:54:32 PM CT	invalidation	Setup Administrator	001-Mathew			
A02BC	True	- Empty -	2/26/2019 5:41:00 AM CT	tmsystem	TBRole	001-Mathew			
Level 4 Term									1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source		
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew			
- Empty -	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew			
- Empty -	True	- Empty -	2/22/2019 6:54:32 PM CT	invalidation	Setup Administrator	001-Mathew			
PROTON PUMP INHIBITORS	True	- Empty -	2/26/2019 5:41:00 AM CT	tmsystem	TBRole	001-Mathew			
Drug Record Number									1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source		
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew			
- Empty -	False	- Empty -	2/22/2019 6:54:32 PM CT	invalidation	Setup Administrator	001-Mathew			
- Empty -	True	- Empty -	2/24/2019 11:49:03 PM CT	stier	CRA	001-Mathew			
012632	True	- Empty -	2/26/2019 5:41:01 AM CT	tmsystem	TBRole	001-Mathew			
WHODrug SEQ1									1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source		
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew			
- Empty -	False	- Empty -	2/22/2019 6:54:32 PM CT	invalidation	Setup Administrator	001-Mathew			
- Empty -	True	- Empty -	2/24/2019 11:49:03 PM CT	stier	CRA	001-Mathew			
04	True	- Empty -	2/26/2019 5:41:01 AM CT	tmsystem	TBRole	001-Mathew			
WHODrug SEQ2									1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source		
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew			
- Empty -	False	- Empty -	2/22/2019 6:54:32 PM CT	invalidation	Setup Administrator	001-Mathew			
- Empty -	True	- Empty -	2/24/2019 11:49:03 PM CT	stier	CRA	001-Mathew			

016	True	- Empty -	2/26/2019 5:41:01 AM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 7386.	2/14/2019 8:46:45 AM CT	imvalidation	Setup Administrator	001-Mathew	
Oral	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 7385.	2/14/2019 8:46:45 AM CT	imvalidation	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:44:39 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 7388.	2/14/2019 8:46:45 AM CT	imvalidation	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	2/14/2019 9:14:56 AM CT	stier	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	dbarber	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	skramer	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	ktrueman	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	gmedina prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	gmedina prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	gmedina prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	gmedina prod	TBMigration

Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-ASPIRIN

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	11
Medication / Therapy Name	ASPIRIN
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	4-SUBARACHNOID HEMORRHAGE
Dose	325
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Daily (QD)
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="radio"/> No <input type="radio"/> Yes
Start Date	<input checked="" type="checkbox"/> 23/OCT/2018 DD/MON/YYYY(EN)
Start Time	UNK:UNK HH:MM
Ongoing	<input checked="" type="radio"/> No <input type="radio"/> Yes
End Date	<input checked="" type="checkbox"/> 29/OCT/2018 DD/MON/YYYY(EN)
End Time	UNK:UNK HH:MM

Verbatim Term	ASPIRIN
Trade Name	ASPIRIN [ACETYLSALICYLIC ACID]
Generic Name	ASPIRIN [ACETYLSALICYLIC ACID]
Level 1 Code	N
Level 1 Term	NERVOUS SYSTEM
Level 2 Code	N02
Level 2 Term	ANALGESICS
Level 3 Code	N02B
Level 3 Term	OTHER ANALGESICS AND ANTIPYRETICS
Level 4 Code	N02BA

Level 4 Term	SALICYLIC ACID AND DERIVATIVES	+
Drug Record Number	000027	+
WHODrug SEQ1	01	+
WHODrug SEQ2	004	+
Route for Coding	Oral	≡
Indication for Coding	SUBARACHNOID HEMORRHAGE	≡
Country for Coding	UNITED STATES	≡

Audit Trail:

iCRF Status History

Status	Date/Time	User	Role	Site
No Data	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/14/2019 8:51:11 AM CT	imvalidation	Setup Administrator	001-Mathew
Monitored	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew
Partial Monitored	2/22/2019 6:54:42 PM CT	imvalidation	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:17 PM CT	istier	CRA	001-Mathew
Partial Monitored	2/26/2019 9:31:26 AM CT	kcheek	Clinical Data Manager (CDM)	001-Mathew
Complete	3/5/2019 1:16:50 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew
Complete	3/5/2019 5:04:54 PM CT	emartin	Clinical Data Manager (CDM)	001-Mathew
Monitored	3/6/2019 10:10:33 AM CT	istier	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	alhunt	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	gmedina	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History

Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
11	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
11	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ASPIRIN	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	

ASPIRIN	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Indication							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	False	MEDICAL CODING: Please confirm this is correct indication, as aspirin can increase bleeding risk. Thanks.	2/26/2019 9:31:26 AM CT	kcheek	Clinical Data Manager (CDM)	001-Mathew	

4-SUBARACHNOID HEMORRHAGE	False	correct per report	3/5/2019 1:16:50 PM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	False	Data updated/provided, query closed.	3/5/2019 5:04:54 PM CT	emartin	Clinical Data Manager (CDM)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	3/6/2019 10:10:33 AM CT	istier	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
325	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
325	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Frequency							1
Field							

Response	Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
QD	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
QD	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Start Date							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
23/OCT/2018	False	(Start Date should be prior to or equal to the Date of Completion or Discontinuation.) CORRECT AS IS	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
23/OCT/2018	True	Correct as entered.	2/14/2019 9:12:19 AM CT	stier	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	2/14/2019 9:12:19 AM CT	stier	CRA	001-Mathew	
Ongoing							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/14/2019 9:12:19 AM CT	stier	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
29/OCT/2018	False	(End date should be prior to or equal to the Date of Completion or Discontinuation.) CORRECT AS IS	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
29/OCT/2018	True	Correct as entered.	2/14/2019 9:12:19 AM CT	stier	CRA	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	2/14/2019 9:12:19 AM CT	stier	CRA	001-Mathew	

Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:51:07 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
ASPIRIN	False	Question value " updated to 'ASPIRIN' by VTS based on DataChange editId 9874.	2/22/2019 6:54:42 PM CT	imvalidation	Setup Administrator	001-Mathew	
ASPIRIN	True	- Empty -	2/24/2019 11:48:17 PM CT	istier	CRA	001-Mathew	
Trade Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:51:11 AM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
ASPIRIN [ACETYLSALICYLIC ACID]	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:51:11 AM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
ASPIRIN [ACETYLSALICYLIC ACID]	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:42 PM CT	imvalidation	Setup Administrator	001-Mathew	

- Empty -	True	- Empty -	2/24/2019 11:48:17 PM CT	stier	CRA	001-Mathew	
N	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:42 PM CT	invalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:17 PM CT	stier	CRA	001-Mathew	
NERVOUS SYSTEM	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:42 PM CT	invalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:17 PM CT	stier	CRA	001-Mathew	
N02	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:42 PM CT	invalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:17 PM CT	stier	CRA	001-Mathew	
ANALGESICS	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:42 PM CT	invalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:17 PM CT	stier	CRA	001-Mathew	
N02B	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:42 PM CT	invalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:17 PM CT	stier	CRA	001-Mathew	

OTHER ANALGESICS AND ANTIPYRETICS			True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code									1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source		
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew			
- Empty -	False	- Empty -	2/14/2019 8:51:11 AM CT	imvalidation	Setup Administrator	001-Mathew			
- Empty -	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew			
N02BA	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew			
Level 4 Term									1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source		
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew			
- Empty -	False	- Empty -	2/14/2019 8:51:11 AM CT	imvalidation	Setup Administrator	001-Mathew			
- Empty -	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew			
SALICYLIC ACID AND DERIVATIVES	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew			
Drug Record Number									1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source		
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew			
- Empty -	False	- Empty -	2/22/2019 6:54:42 PM CT	imvalidation	Setup Administrator	001-Mathew			
- Empty -	True	- Empty -	2/24/2019 11:48:17 PM CT	istier	CRA	001-Mathew			
000027	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew			
WHODrug SEQ1									1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source		
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew			
- Empty -	False	- Empty -	2/22/2019 6:54:42 PM CT	imvalidation	Setup Administrator	001-Mathew			
- Empty -	True	- Empty -	2/24/2019 11:48:17 PM CT	istier	CRA	001-Mathew			
01	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew			
WHODrug SEQ2									1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source		
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew			
- Empty -	False	- Empty -	2/22/2019 6:54:42 PM CT	imvalidation	Setup Administrator	001-Mathew			
- Empty -	True	- Empty -	2/24/2019 11:48:17 PM CT	istier	CRA	001-Mathew			

004	True	- Empty -	3/6/2019 6:17:01 AM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 7386.	2/14/2019 8:51:11 AM CT	imvalidation	Setup Administrator	001-Mathew	
Oral	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 7385.	2/14/2019 8:51:11 AM CT	imvalidation	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:49:34 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 7388.	2/14/2019 8:51:11 AM CT	imvalidation	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	2/14/2019 9:12:19 AM CT	istier	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	dbarber	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	skramer	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	ktrueman	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	gmedina prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	gmedina prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	gmedina prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	gmedina prod	TBMigration



Trial Number: 22ndC_VLN
Subject Caption: 001023
Subject Number: 001023

Visit Name:
Visit Date:
Current Time:

iCRF Status: Signed Locked
Subject Initials:

CM-PLAVIX

Record all prior and concomitant medications taken from within 30 days prior to screening up to end of study.

Concomitant Medication Number	12
Medication / Therapy Name	PLAVIX
Indication	Adverse Event
Primary Medical History Term	
Primary Adverse Event Term	4-SUBARACHNOID HEMORRHAGE
Dose	75
Unit	Milligram
Dose Form	Tablet; tab
Frequency	Daily (QD)
Route	Oral
Was the medication/therapy taken prior to the study?	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
Start Date	 23/OCT/2018 DD/MON/YYYY(EN)
Start Time	UNK:UNK HH:MM
Ongoing	<input checked="" type="radio"/> No <input checked="" type="radio"/> Yes
End Date	 29/OCT/2018 DD/MON/YYYY(EN)
End Time	UNK:UNK HH:MM

Verbatim Term	PLAVIX
Trade Name	PLAVIX
Generic Name	CLOPIDOGREL BISULFATE
Level 1 Code	B
Level 1 Term	BLOOD AND BLOOD FORMING ORGANS
Level 2 Code	B01
Level 2 Term	ANTITHROMBOTIC AGENTS
Level 3 Code	B01A
Level 3 Term	ANTITHROMBOTIC AGENTS
Level 4 Code	B01AC

Level 4 Term	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	+
Drug Record Number	012207	+
WHODrug SEQ1	07	+
WHODrug SEQ2	002	+
Route for Coding	Oral	≡
Indication for Coding	SUBARACHNOID HEMORRHAGE	≡
Country for Coding	UNITED STATES	≡

Audit Trail:

iCRF Status History				
Status	Date/Time	User	Role	Site
No Data	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew
Complete	2/14/2019 8:52:52 AM CT	imvalidation	Setup Administrator	001-Mathew
Monitored	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew
Partial Monitored	2/22/2019 6:54:53 PM CT	imvalidation	Setup Administrator	001-Mathew
Monitored	2/24/2019 11:48:51 PM CT	stier	CRA	001-Mathew
Signed	3/12/2019 1:34:45 PM CT	alhunt	Principal Investigator	001-Mathew
Signed Locked	3/13/2019 11:04:11 AM CT	gmedina	Trial Manager (Celerion)	001-Mathew

iCRF Item Change History							
Question Audit History							
Concomitant Medication Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
12	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
12	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
Medication / Therapy Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
PLAVIX	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
PLAVIX	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
Indication							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

	Monitored?						
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ADVERSE EVENT	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
If Other Indication, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
Primary Medical History Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
Primary Adverse Event Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
4-SUBARACHNOID HEMORRHAGE	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
Dose							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
75	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
75	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
Unit							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
mg	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
mg	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
If Other Unit, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
Dose Form							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
TABLET	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
Frequency							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
QD	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
QD	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
If Other Frequency, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
Route							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source

- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
ORAL	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
If Other Route, specify							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
Was the medication/therapy taken prior to the study?							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
Start Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
23/OCT/2018	False	(Start Date should be prior to or equal to the Date of Completion or Discontinuation.) CORRECT AS IS	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
23/OCT/2018	True	Correct as entered.	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
Start Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
Ongoing							1
Response	Field Moni	Notes	Date/Time	User	Role	Site	Source

	tored?						
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
N	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
N	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
End Date							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
29/OCT/2018	False	(End date should be prior to or equal to the Date of Completion or Discontinuation.) CORRECT AS IS	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
29/OCT/2018	True	Correct as entered.	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
End Time							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNK:UNK	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
Not true data. Flag used for CM Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:52:51 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
Verbatim Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina	prod TBMigration	001-Mathew	
PLAVIX	False	Question value " updated to 'PLAVIX' by VTS based on DataChange editId 9874.	2/22/2019 6:54:53 PM CT	invalidation	Setup Administrator	001-Mathew	
PLAVIX	True	- Empty -	2/24/2019 11:48:51 PM CT	stier	CRA	001-Mathew	
Trade Name							1

Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:52:52 AM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
PLAVIX	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Generic Name							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:52:52 AM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
CLOPIDOGREL BISULFATE	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:53 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:51 PM CT	istier	CRA	001-Mathew	
B	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 1 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:53 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:51 PM CT	istier	CRA	001-Mathew	
BLOOD AND BLOOD FORMING ORGANS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:53 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:51 PM CT	istier	CRA	001-Mathew	

B01	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 2 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina	prod TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:53 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:51 PM CT	stier	CRA	001-Mathew	
ANTITHROMBOTIC AGENTS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina	prod TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:53 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:51 PM CT	stier	CRA	001-Mathew	
B01A	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 3 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina	prod TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:53 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:51 PM CT	stier	CRA	001-Mathew	
ANTITHROMBOTIC AGENTS	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Code							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
- Empty -	False	- Empty -	2/14/2019 8:52:52 AM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
B01AC	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Level 4 Term							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	

- Empty -	False	- Empty -	2/14/2019 8:52:52 AM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Drug Record Number							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:53 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:51 PM CT	stier	CRA	001-Mathew	
012207	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ1							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:53 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:51 PM CT	stier	CRA	001-Mathew	
07	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
WHODrug SEQ2							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/18/2019 4:31:19 PM CT	gmedina_prod	TBMigration	001-Mathew	
- Empty -	False	- Empty -	2/22/2019 6:54:53 PM CT	imvalidation	Setup Administrator	001-Mathew	
- Empty -	True	- Empty -	2/24/2019 11:48:51 PM CT	stier	CRA	001-Mathew	
002	True	- Empty -	2/25/2019 2:38:03 PM CT	tmsystem	TBRole	001-Mathew	
Route for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
Oral	False	Question value " updated to 'Oral' by VTS based on DataChange editId 7386.	2/14/2019 8:52:52 AM CT	imvalidation	Setup Administrator	001-Mathew	
Oral	True	- Empty -	2/14/2019 9:13:40 AM CT	stier	CRA	001-Mathew	
Indication for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	

SUBARACHNOID HEMORRHAGE	False	Question value " updated to 'SUBARACHNOID HEMORRHAGE' by VTS based on DataChange editId 7385.	2/14/2019 8:52:52 AM CT	imvalidation	Setup Administrator	001-Mathew	
SUBARACHNOID HEMORRHAGE	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	
Country for Coding							1
Response	Field Monitored?	Notes	Date/Time	User	Role	Site	Source
- Empty -	False	- Empty -	2/14/2019 8:51:19 AM CT	sbradford	Clinical Research Coordinator (CRC)	001-Mathew	
UNITED STATES	False	Question value " updated to 'UNITED STATES' by VTS based on DataChange editId 7388.	2/14/2019 8:52:52 AM CT	imvalidation	Setup Administrator	001-Mathew	
UNITED STATES	True	- Empty -	2/14/2019 9:13:40 AM CT	istier	CRA	001-Mathew	

iCRF Version Change History

Date	Change	Version	User	Role
13/AUG/2018 09:08:17 CT	Publish	Base Version	dbarber	TBRole
07/OCT/2018 22:58:39 CT	Mid-study changes	MSC001	skramer	TBMigration
18/DEC/2018 13:51:12 CT	Mid-study changes	MSC002	ktrueman	TBMigration
07/FEB/2019 15:23:08 CT	Mid-study changes	MSC003	gmedina prod	TBMigration
13/FEB/2019 10:43:54 CT	Mid-study changes	MSC004	gmedina prod	TBMigration
18/FEB/2019 16:31:19 CT	Mid-study changes	MSC005	gmedina prod	TBMigration
22/FEB/2019 18:35:29 CT	Mid-study changes	MSC006	gmedina prod	TBMigration

Below list includes all users that have or had signature permissions. Each row indicates the effective date range for the username and full name combination. Blank dates in the “To” column signify electronic signature was still in effect as of the date the PDF was generated.

Electronic Signature Manifestations				
User	From	To	Full Name	Signature Meaning
alhunt	11/JAN/2019 11:41:35 CT		Allen Hunt	By providing my electronic signature, I certify that I have reviewed the data.

All timestamps in this report are in (GMT-06:00) Central Time (US & Canada) timezone.



16.3.2 All Case Report Forms

Available upon request.