

Subject Case Report Forms

1150 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 15:37:47

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Form: Subject

Data signed: (hfarmer1) 27 Mar 2015 14:22:13

Generated On: 20 Jul 2016 15:37:47

Screening number	1150
------------------	------

Site number	DAY
-------------	-----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 27 Mar 2015 14:22:13

Generated On: 20 Jul 2016 15:37:47

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

28 FEB 2014
DD/MMM/YYYY

Randomization Time

13:41
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Date of Visit

03 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 27 Mar 2015 14:22:13

Generated On: 20 Jul 2016 15:37:47

Has the subject given written informed consent for
Bio-banking for Biomarkers of Exposure and Risk
Markers?

Yes ☒

Consent Date

03 FEB 2014
DD/MMM/YYYY

Has the subject given written informed consent for
Bio-banking for Transcriptomics (Pharmacogenomics),
Nasal Epithelial collection and Buccal Collection?

Yes ☒

Consent Date

03 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Inclusion Criterion Number	1
----------------------------	---

Inclusion Criterion	Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF.
---------------------	---

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Inclusion Criterion Number	2
----------------------------	---

Inclusion Criterion	Subject is at a minimum 22 years of age(inclusive).
---------------------	--

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Inclusion Criterion Number

3

Inclusion Criterion

Smoking, apparently healthy subject as judged by the Investigator based on all available assessments from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination, ECG, chest X-ray, and medical history).

Result

Yes

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Inclusion Criterion Number	4
----------------------------	---

Inclusion Criterion	Subject smokes at least 10 commercially available mCCs per day (no brand restrictions), for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).
---------------------	---

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Inclusion Criterion Number	5
----------------------------	---

Inclusion Criterion	The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire.
---------------------	--

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Inclusion Criterion Number	6
----------------------------	---

Inclusion Criterion	The subject is ready to comply with study protocol (e.g readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol).
---------------------	---

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	1
----------------------------	---

Exclusion Criterion	As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason).
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	2
----------------------------	---

Exclusion Criterion	A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated).
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number

3

Exclusion Criterion

The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.

Result

No

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	4
----------------------------	---

Exclusion Criterion	Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013).
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	5
----------------------------	---

Exclusion Criterion	Subject with asthma condition (FEV1/FVC < 0.75 and reversibility in FEV1 > 12% (or > 200 mL) from pre to post-bronchodilator values).
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	6
----------------------------	---

Exclusion Criterion	Subjects with renal insufficiency as defined by serum creatinine levels of >1.3 mg/dL for females and >1.5 mg/dL for males.
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	7
----------------------------	---

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m ² .
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	8
----------------------------	---

Exclusion Criterion	As per Investigator judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results.
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	9
----------------------------	---

Exclusion Criterion	Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy.
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	10
----------------------------	----

Exclusion Criterion	The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or NRT), as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment.
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	12
----------------------------	----

Exclusion Criterion	<p>If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety.</p>
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	13
----------------------------	----

Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	14
----------------------------	----

Exclusion Criterion	The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with the subject's participation in the study.
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	15
----------------------------	----

Exclusion Criterion	The subject has a positive urine drug test. <input checked="" type="radio"/>
---------------------	--

Result	No <input type="radio"/>
--------	--------------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	16
----------------------------	----

Exclusion Criterion	Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B or hepatitis C.	<input checked="" type="radio"/>
---------------------	--	----------------------------------

Result	No	<input type="radio"/>
--------	----	-----------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	17
----------------------------	----

Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission.	<input checked="" type="radio"/>
---------------------	--	----------------------------------

Result	No	<input type="radio"/>
--------	----	-----------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	18
----------------------------	----

Exclusion Criterion	The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).
---------------------	--

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	19
----------------------------	----

Exclusion Criterion	The subject is an employee of the investigational site or any other parties involved in the study or of their first degree relatives (parent, sibling, and child).
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	20
----------------------------	----

Exclusion Criterion	The subject has participated in a clinical study within 3 months prior to the Screening Visit.
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	21
----------------------------	----

Exclusion Criterion	For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.
---------------------	--

Result	NA
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	22
----------------------------	----

Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception
---------------------	---

Result	NA
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 27 Mar 2015 14:22:13

Generated On: 20 Jul 2016 15:37:47

Date of Birth	(b) (6)
Sex	Male
Race	White
Other, specify	
Ethnicity	Not Hispanic
Date the Subject signed the Informed Consent	03 FEB 2014 DD/MMM/YYYY
Time the Subject signed the Informed Consent	11:03 hour:min 24-hour clock
Age(Derived)	24

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hfarmer1) 27 Mar 2015 14:22:15

Generated On: 20 Jul 2016 15:37:47

Date of collection

03 FEB 2014
DD/MMM/YYYY

Has the subject experienced any past and/ or
concomitant diseases?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:15

Generated On: 20 Jul 2016 15:37:47

Date of collection	03 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	1
--------	---

Diagnosis Description	TONSILS REMOVED
-----------------------	-----------------

Onset Date DD/MMM/YYYY	UN UNK 1993
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 1993
--------------------------	-------------

Ongoing?	False
----------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:15

Generated On: 20 Jul 2016 15:37:47

Date of collection	03 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	2
--------	---

Diagnosis Description	DENTAL EXTRACTIONS, 2 BOTTOM TEETH PULLED
-----------------------	--

Onset Date DD/MMM/YYYY	UN UNK 2007
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 2007
--------------------------	-------------

Ongoing?	False
----------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Medical History/Concomitant Disease (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:15

Generated On: 20 Jul 2016 15:37:47

Date of collection	03 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	3
--------	---

Diagnosis Description	FEMUR FRACTURE, RIGHT, CASTING
-----------------------	-----------------------------------

Onset Date DD/MMM/YYYY	UN UNK 1993
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 1993
--------------------------	-------------

Ongoing?	False
----------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Medical History/Concomitant Disease (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:15

Generated On: 20 Jul 2016 15:37:47

Date of collection	03 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	4
--------	---

Diagnosis Description	INSOMNIA
-----------------------	----------

Onset Date DD/MMM/YYYY	UN UNK 2012
---------------------------	-------------

Stop Date DD/MMM/YYYY	
--------------------------	--

Ongoing?	True
----------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Medical History/Concomitant Disease (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:15

Generated On: 20 Jul 2016 15:37:47

Date of collection	03 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	5
--------	---

Diagnosis Description	ERYTHROMYCIN ALLERGY
-----------------------	----------------------

Onset Date DD/MMM/YYYY	UN UNK 1997
---------------------------	-------------

Stop Date DD/MMM/YYYY	
--------------------------	--

Ongoing?	True
----------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment No ☒

Date of assessment 03 FEB 2014
DD/MMM/YYYY

Time of assessment 12:30
hour:min 24-hour clock

Pulse rate 63
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 117
mmHg

Blood Pressure (diastolic) 66
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

03 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

03 FEB 2014
DD/MMM/YYYY

System

HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Back ☐

Outcome Normal ☐

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 03 FEB 2014
DD/MMM/YYYY

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify SEVERAL DECAYED AND
BROKEN TEETH

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

03 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

03 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

03 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

03 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:22:16

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

03 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 27 Mar 2015 14:22:27

Generated On: 20 Jul 2016 15:37:47

Date

03 FEB 2014
DD/MMM/YYYY

Brand name

305 MENTHOL 100'S

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Has the subject seen a THS 2.2 menthol product
demonstration?

Yes ☒

If the subject did not see the demonstration please
explain

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Date of Assessment

03 FEB 2014
DD/MMM/YYYY

1. Does the subject plan to quit smoking during the next
6 months?

No ☐

2. Did the subject smoke for at least 3 consecutive
years?

Yes ☐

3. How many menthol cigarettes per day has the subject
smoked on average during the last 4 weeks?

>19 ☐

4. Did the subject smoke menthol cigarettes in the last 4
weeks?

Yes ☐

5. The subject has used nicotine-containing products
other than commercially available mCC (either
tobacco-based products or nicotine-replacement therapy
[NRT]), electronic cigarettes and similar devices, within 4
weeks prior to assessment.

No ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

03 FEB 2014
DD/MMM/YYYY

Weight

79.4
kg

Height

172
cm

BMI (Derived)

26.8
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:22:13

Generated On: 20 Jul 2016 15:37:47

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 03 FEB 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 66
beats per minute

QRS Interval 97
msec

QT Interval 366
msec

QTcB Interval 384
msec

QTcF Interval 378
msec

PR Interval 136
msec

Interpretation Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:22:13

Generated On: 20 Jul 2016 15:37:47

If Abnormal, Clinical Significance _____

If Not Clinically significant or clinically Significant, Please
specify the finding(s) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:27

Generated On: 20 Jul 2016 15:37:47

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting ☒
bronchodilator

Position SITTING

Has the subject smoked within 1 hour prior to assessment? No ☒

Date of assessment 03 FEB 2014
DD/MMM/YYYY

Time of assessment 13:18

Predicted FVC value 5.18
L

Best measured FVC value 5.90
L

Percent of predicted FVC value 114
%

Best measured FEV1 value 4.02
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:27

Generated On: 20 Jul 2016 15:37:47

Predicted FEV1 value	4.31 L
----------------------	-----------

Percent of predicted FEV1 value	93 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	0.68
-----------------------------------	------

MEF 25/75 value	2.37 L/s
-----------------	-------------

Interpretation	Normal <input checked="" type="radio"/>
----------------	---

If Abnormal, Clinical Significance	<hr/>
------------------------------------	-------

If Not Clinically Significant or Clinically Significant, Please specify the finding(s)	<hr/>
---	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:27

Generated On: 20 Jul 2016 15:37:47

Was the spirometry performed? Yes ☐

If No, please specify the reason: _____

Category With short-acting ☐
bronchodilator

Position SITTING

Has the subject smoked within 1 hour prior to assessment? No ☐

Date of assessment 03 FEB 2014
DD/MMM/YYYY

Time of assessment 13:53

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 5.18
L

Best measured FVC value 5.27
L

Percent of predicted FVC value 102
%

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:27

Generated On: 20 Jul 2016 15:37:47

Best measured FEV1 value	3.99 L
--------------------------	-----------

Predicted FEV1 value	4.31 L
----------------------	-----------

Percent of predicted FEV1 value	92 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	0.76
-----------------------------------	------

MEF 25/75 value	3.38 L/s
-----------------	-------------

Interpretation	Normal <input checked="" type="radio"/>
----------------	---

If Abnormal, Clinical Significance	<hr/>
------------------------------------	-------

If Not Clinically Significant or Clinically Significant, Please specify the finding(s)	<hr/>
---	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Was a chest X-Ray with anterior-posterior and left lateral
views performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

11 FEB 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:22:15

Generated On: 20 Jul 2016 15:37:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:22:15

Generated On: 20 Jul 2016 15:37:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 27 Mar 2015 14:22:15

Generated On: 20 Jul 2016 15:37:47

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Not Done?	False
-----------	-------

If Not Done, please specify the reason: _____

Date of sample collection	03 FEB 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	12:10 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 03 FEB 2014
DD/MMM/YYYY

Time of assessment 12:16
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 27 Mar 2015 14:22:14

Generated On: 20 Jul 2016 15:37:47

Category	Cotinine Screening <input checked="" type="radio"/>
----------	---

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date of Sample Collection	03 FEB 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	12:10 hour:min 24-hour clock
---------------------------	---------------------------------

Result	Positive >=200 ng/ml <input checked="" type="radio"/>
--------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(03 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(03 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
-----------------	-----------

Date of Sample Collection YYYY/MM/DD	03 FEB 2014
---	-------------

Subject Number	
----------------	--

Date of Birth	(b) (6)
---------------	---------

Gender	Male <input checked="" type="radio"/>
--------	---------------------------------------

Time of Sample Collection	13:11
---------------------------	-------

Analyte Name	GLUCOSE, SERUM
--------------	----------------

Code	001032
------	--------

Result	83
--------	----

Unit	MG/DL
------	-------

Lower limit	65
-------------	----

Upper limit	99
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(03 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
-----------------	-----------

Date of Sample Collection YYYY/MM/DD	03 FEB 2014
---	-------------

Subject Number	
----------------	--

Date of Birth	(b) (6)
---------------	---------

Gender	Male <input checked="" type="radio"/>
--------	---------------------------------------

Time of Sample Collection	13:11
---------------------------	-------

Analyte Name	BUN
--------------	-----

Code	001040
------	--------

Result	8
--------	---

Unit	MG/DL
------	-------

Lower limit	6
-------------	---

Upper limit	20
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	CHOLESTEROL, TOTAL
Code	001065
Result	146
Unit	MG/DL
Lower limit	100
Upper limit	189
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	PROTEIN, TOTAL, SERUM
Code	001073
Result	6.7
Unit	G/DL
Lower limit	6.0
Upper limit	8.5
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

ALBUMIN, SERUM

Code

001081

Result

4.7

Unit

G/DL

Lower limit

3.5

Upper limit

5.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	BILIRUBIN, TOTAL
Code	001099
Result	0.5
Unit	MG/DL
Lower limit	0.0
Upper limit	1.2
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	ALKALINE PHOSPHATASE, S
Code	001107
Result	57
Unit	IU/L
Lower limit	39
Upper limit	117
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	LDH
Code	001115
Result	138
Unit	IU/L
Lower limit	0
Upper limit	225
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

AST (SGOT)

Code

001123

Result

19

Unit

IU/L

Lower limit

0

Upper limit

40

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	TRIGLYCERIDES
Code	001172
Result	107
Unit	MG/DL
Lower limit	0
Upper limit	114
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

POTASSIUM, SERUM

Code

001180

Result

4.5

Unit

MMOL/L

Lower limit

3.5

Upper limit

5.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	SODIUM, SERUM
Code	001198
Result	138
Unit	MMOL/L
Lower limit	134
Upper limit	144
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	BILIRUBIN, DIRECT
Code	001222
Result	0.20
Unit	MG/DL
Lower limit	0.00
Upper limit	0.40
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	CREATININE, SERUM
Code	001370
Result	0.73
Unit	MG/DL
Lower limit	0.76
Upper limit	1.27
Flag	Low <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

ALT (SGPT)

Code

001545

Result

15

Unit

IU/L

Lower limit

0

Upper limit

44

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type	CHEMISTRY
-----------------	-----------

Date of Sample Collection YYYY/MM/DD	03 FEB 2014
---	-------------

Subject Number	
----------------	--

Date of Birth	(b) (6)
---------------	---------

Gender	Male <input checked="" type="radio"/>
--------	---------------------------------------

Time of Sample Collection	13:11
---------------------------	-------

Analyte Name	GGT
--------------	-----

Code	001958
------	--------

Result	17
--------	----

Unit	IU/L
------	------

Lower limit	0
-------------	---

Upper limit	65
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

HEP C VIRUS AB

Code

140683

Result

<0.1

Unit

S/CO RATIO

Lower limit

0.0

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:22:28

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(03 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:31

Generated On: 20 Jul 2016 15:37:47

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(03 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:31

Generated On: 20 Jul 2016 15:37:47

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

HIV 1/O/2 ABS, QUAL

Code

001725

Result

NON REACTIVE

Unit

Lower limit

NON REACTIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(03 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:31

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:31

Generated On: 20 Jul 2016 15:37:47

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

HBSAG SCREEN

Code

006510

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:31

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:31

Generated On: 20 Jul 2016 15:37:47

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

HIV 1/O/2 ABS-INDEX VALUE

Code

150010

Result

<1.00

Unit

Lower limit

<1.00

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:31

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(03 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(03 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	WBC
Code	005025
Result	13.3
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(03 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	RBC
Code	005033
Result	5.82
Unit	X10E6/UL
Lower limit	4.14
Upper limit	5.80
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	HEMOGLOBIN
Code	005041
Result	18.2
Unit	G/DL
Lower limit	12.6
Upper limit	17.7
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

HEMATOCRIT

Code

005058

Result

53.2

Unit

%

Lower limit

37.5

Upper limit

51.0

Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	MCV
Code	015065
Result	91
Unit	FL
Lower limit	79
Upper limit	97
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	MCH
Code	015073
Result	31.3
Unit	PG
Lower limit	26.6
Upper limit	33.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	MCHC
Code	015081
Result	34.2
Unit	G/DL
Lower limit	31.5
Upper limit	35.7
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	NEUTROPHILS
Code	015107
Result	75
Unit	%
Lower limit	40
Upper limit	74
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	LYMPHS
Code	015123
Result	20
Unit	%
Lower limit	14
Upper limit	46
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	MONOCYTES
Code	015131
Result	4
Unit	%
Lower limit	4
Upper limit	12
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	EOS
Code	015149
Result	1
Unit	%
Lower limit	0
Upper limit	5
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

BASOS

Code

015156

Result

0

Unit

%

Lower limit

0

Upper limit

3

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

PLATELETS

Code

015172

Result

227

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

NEUTROPHILS (ABSOLUTE)

Code

015909

Result

9.9

Unit

X10E3/UL

Lower limit

1.4

Upper limit

7.0

Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

LYMPHS (ABSOLUTE)

Code

015917

Result

2.7

Unit

X10E3/UL

Lower limit

0.7

Upper limit

3.1

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

03 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:11

Analyte Name

MONOCYTES(ABSOLUTE)

Code

015925

Result

0.6

Unit

X10E3/UL

Lower limit

0.1

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	EOS (ABSOLUTE)
Code	015933
Result	0.2
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.4
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	03 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:11
Analyte Name	BASO (ABSOLUTE)
Code	015941
Result	0.0
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.2
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 27 Mar 2015 14:22:32

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03457100190

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(3 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

3 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(3 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

3 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:31

Analyte Name

SPECIFIC GRAVITY

Code

13060

Result

1.005

Unit

Lower limit

1.001

Upper limit

1.035

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(3 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	3 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	12:31
Analyte Name	PH
Code	13078
Result	8
Unit	
Lower limit	5
Upper limit	8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

3 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

12:31

Analyte Name

GLUCOSE

Code

13086

Result

NORMAL

Unit

Lower limit

NORMAL

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

3 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:31

Analyte Name

PROTEIN

Code

13094

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

3 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:31

Analyte Name

OCCULT BLOOD

Code

13102

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

3 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:31

Analyte Name

BILIRUBIN

Code

13104

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

3 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:31

Analyte Name

NITRITE, URINE

Code

13106

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 15:37:47

Type	FTND
------	------

Date of Birth	(b) (6)
---------------	---------

Date of assessment	2014 FEB 03
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	14:05
	hour:min 24-hour clock

Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

1. How soon after you wake up do you smoke your first cigarette?	31-60 minutes <input checked="" type="radio"/>
--	--

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	No <input checked="" type="radio"/>
--	-------------------------------------

3. Which cigarette would you hate most to give up?	The first in the morning <input checked="" type="radio"/>
--	---

4. How many cigarettes per day do you smoke?	11-20 <input checked="" type="radio"/>
--	--

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?	Yes <input checked="" type="radio"/>
---	--------------------------------------

6. Do you smoke even if you are so ill that you are in bed most of the day?	Yes <input checked="" type="radio"/>
---	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Screening

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 27 Mar 2015 14:22:27

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 03 FEB 2014
DD/MMM/YYYY

Time of assessment 11:25
hour:min 24-hour clock

1. Are you currently a smoker? Yes, I currently smoke ☒

2. In the last year, how many times have you quit
smoking for at least 24 hours? 0

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Date of Visit

26 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:22:35

Generated On: 20 Jul 2016 15:37:47

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:35

Generated On: 20 Jul 2016 15:37:47

Inclusion Criterion Number	3
----------------------------	---

Inclusion Criterion	Smoking, apparently healthy subject as judged by the Investigator based on all available assessments from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination, ECG, chest X-ray, and medical history).
---------------------	--

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:35

Generated On: 20 Jul 2016 15:37:47

Inclusion Criterion Number	4
----------------------------	---

Inclusion Criterion	Subject smokes at least 10 commercially available mCCs per day (no brand restrictions), for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).
---------------------	---

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:35

Generated On: 20 Jul 2016 15:37:47

Inclusion Criterion Number	5
----------------------------	---

Inclusion Criterion	The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire.
---------------------	--

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:35

Generated On: 20 Jul 2016 15:37:47

Inclusion Criterion Number	6
----------------------------	---

Inclusion Criterion	The subject is ready to comply with study protocol (e.g readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol).	<input checked="" type="radio"/>
---------------------	--	----------------------------------

Result	Yes	<input checked="" type="radio"/>
--------	-----	----------------------------------

*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	1
----------------------------	---

Exclusion Criterion	As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason).
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number

3

Exclusion Criterion

The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.

Result

No

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	7
----------------------------	---

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m ² .
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	8
----------------------------	---

Exclusion Criterion	As per Investigator judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results.
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	9
----------------------------	---

Exclusion Criterion	Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy.
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	10
----------------------------	----

Exclusion Criterion	The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or NRT), as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment.
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	11
----------------------------	----

Exclusion Criterion	The subject has received medication (prescription or over-the-counter) within 14 days or within five half-lives of the drug (whichever is longer) prior to the Admission Day (Day -2), which has an impact on CYP1A2 or CYP2A6 activity.
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	12
----------------------------	----

Exclusion Criterion	If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety.
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	13
----------------------------	----

Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	14
----------------------------	----

Exclusion Criterion	The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with the subject's participation in the study.
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	15
----------------------------	----

Exclusion Criterion	The subject has a positive urine drug test. <input checked="" type="radio"/>
---------------------	--

Result	No <input type="radio"/>
--------	--------------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	17
----------------------------	----

Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission.
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	21
----------------------------	----

Exclusion Criterion	For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.
---------------------	--

Result	NA
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Exclusion Criterion Number	22
----------------------------	----

Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception
---------------------	---

Result	NA
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment No ☒

Time of assessment 12:00
hour:min 24-hour clock

Pulse rate 78
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 135
mmHg

Blood Pressure (diastolic) 72
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Which Product Arm would you prefer to be randomized
to:

mCC ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Back ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify DECAVED AND BROKEN
TEETH

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:22:36

Generated On: 20 Jul 2016 15:37:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hcoleman1) 18 Jun 2015 21:00:56

Generated On: 20 Jul 2016 15:37:47

Brand name

MARLBORO BLACK 100'S
MENTHOL

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Was the THS 2.2 menthol product trial performed?

Yes ☒

If the THS 2.2 menthol product trial was not performed,
please explain _____

How many THS 2.2 menthol tobacco sticks did the
subject use on this day?

1

Is the subject willing and able to use the product during
the study?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

2. Did the subject smoke for at least 3 consecutive years? Yes ☐

3. How many menthol cigarettes per day has the subject smoked on average during the last 4 weeks? 10 to 19 ☐

4. Did the subject smoke menthol cigarettes in the last 4 weeks? Yes ☐

5. The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or nicotine-replacement therapy [NRT]), electronic cigarettes and similar devices, within 4 weeks prior to assessment. No ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

11:42
hour:min 24-hour clock

Weight

79.7
kg

Waist circumference

92
cm

BMI

26.9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 27 Mar 2015 14:22:35

Generated On: 20 Jul 2016 15:37:47

Not Done?	False
-----------	-------

If Not Done, please specify the reason: _____

Time of sample collection	11:40
	hour:min 24-hour clock

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative
Cannabinoids	Negative
Cocaine	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:35

Generated On: 20 Jul 2016 15:37:47

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 27 Mar 2015 14:22:35

Generated On: 20 Jul 2016 15:37:47

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 11:54
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 27 Mar 2015 14:22:34

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	11:52
	hour:min 24-hour clock

Result	49
	ppm

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Admission (Day -2)

Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 26 FEB 2014
DD/MMM/YYYY

Time of assessment 12:07
hour:min 24-hour clock

1. Are you currently a smoker? Yes, I currently smoke ☒

2. In the last year, how many times have you quit smoking for at least 24 hours? 0

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:22:41

Generated On: 20 Jul 2016 15:37:47

Date of Visit

27 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment No ☒

Time of assessment 09:35
hour:min 24-hour clock

Pulse rate 67
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 122
mmHg

Blood Pressure (diastolic) 71
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 FEB 2014
---------------------	-------------

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	20:45
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:20
---	-------

Result(ppm)	21
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	12:04
---	-------

Result(ppm)	41
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:47
---	-------

Result(ppm)	56
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:37

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	20:42
---	-------

Result(ppm)	45
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

Data signed: (hfarmer1) 27 Mar 2015 14:22:41

Generated On: 20 Jul 2016 15:37:47

Start Time	10:01
	hour:min 24-hour clock

End Time	13:58
	hour:min 24-hour clock

Volume	786
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

Data signed: (hfarmer1) 27 Mar 2015 14:22:41

Generated On: 20 Jul 2016 15:37:47

Were samples for 4h collected? Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected? 13

How many back up tubes were collected? 13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115150001329
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	-1
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Date of Birth

(b) (6)

Date of assessment

2014 FEB 27

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:05

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

A lot ☒

2. Did cigarettes taste good?

Moderately ☒

3. Did you enjoy the sensation in your throat and chest?

Moderately ☒

4. Did smoking calm you down?

A lot ☒

5. Did smoking make you feel more awake?

Moderately ☒

6. Did smoking make you feel less irritable?

Moderately ☒

7. Did smoking help you concentrate?

A lot ☒

8. Did smoking reduce your hunger for food?

Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

9. Did smoking make you dizzy? Little ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a
cigarette? A lot ☐

12. Did you enjoy smoking? Moderately ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Type	BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:58 hour:min 24-hour clock
--------------------	---------------------------------

Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
---	---------------------------

Do you now smoke cigarettes every day, some days, or not at all?	Every day <input type="radio"/>
--	---------------------------------

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?	No <input type="radio"/>
--	--------------------------

How long has it been since you last smoked a cigarette, even one or two puffs?	<hr/>
--	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Do you currently use chewing tobacco, snuff, or snus
every day, some days, or not at all?

Not at all ☐

NOTE: Snus (Swedish for snuff) is a moist smokeless
tobacco, usually sold in small pouches that are placed
under the lip against the gum.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	22:02 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years 00 Years

Months 00 Months

Days 00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL BLACK 100'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	22:02 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/>
--	---

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
--	---------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input type="radio"/>
--	---------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL BLACK 100'S

Time

Currently (last 3 months) ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day?

Manufactured Cigarettes
per day

020

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

8. On average, how many cigars do/did you smoke per
day?

None ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	22:02 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years 00 Years

Months 00 Months

Days 00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL BLACK 100'S

Time 1 year ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day?

Manufactured Cigarettes per day 016

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☒

Hand-rolled Cigarettes per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

8. On average, how many cigars do/did you smoke per
day?

None ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	22:02 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years 00 Years

Months 00 Months

Days 00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL BLACK 100'S

Time 5 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day?

Manufactured Cigarettes per day 012

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☒

Hand-rolled Cigarettes per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

8. On average, how many cigars do/did you smoke per
day?

None ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	22:02 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL BLACK 100'S

Time

10 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day?

Manufactured Cigarettes
per day

010

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

8. On average, how many cigars do/did you smoke per
day?

None ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	22:02 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL BLACK 100'S

Time

15 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day?

None ☒

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

8. On average, how many cigars do/did you smoke per
day?

None ☒

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	22:02 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years 00 Years

Months 00 Months

Days 00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL BLACK 100'S

Time 20 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☒

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

8. On average, how many cigars do/did you smoke per
day?

None ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	22:02 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/>
--	---

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
--	---------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input type="radio"/>
--	---------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL BLACK 100'S

Time

More than 20 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day?

None ☒

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:38

Generated On: 20 Jul 2016 15:37:47

8. On average, how many cigars do/did you smoke per
day?

None ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☐

Pipes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Supplemental Questions

Data signed: (hfarmer1) 27 Mar 2015 14:22:41

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 22:03

1. How long it takes for the subject to complete the SQ 03 minutes

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:41

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 22:03

1. How long it takes for the subject to complete the SQ 03 minutes

Question 2. Did the SQ capture your smoking behavior completely? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:41

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 22:03

1. How long it takes for the subject to complete the SQ 03 minutes

Question 3. Did the SQ capture your smoking behavior correctly? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:41

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 22:03

1. How long it takes for the subject to complete the SQ 03 minutes

Question 4. Did the SQ capture your smoking history completely? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:41

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 22:03

1. How long it takes for the subject to complete the SQ 03 minutes

Question 5. Did the SQ capture your smoking history correctly? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:41

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 22:03

1. How long it takes for the subject to complete the SQ 03 minutes

Question 6. Was the SQ ☐
self-explaining?

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:41

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 22:03

1. How long it takes for the subject to complete the SQ 03 minutes

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 FEB 27
DD/MMM/YYYY	
Time of assessment	20:04
hour:min 24-hour clock	
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Somewhat agree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Somewhat agree <input type="radio"/>
3. If it were possible I would probably smoke now	Agree <input type="radio"/>
4. I could control things better right now if I could smoke	Agree <input type="radio"/>
5. All I want right now is a cigarette	Agree <input type="radio"/>
6. I have an urge for a cigarette	Somewhat agree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

7. A cigarette would taste good now Agree ☐

8. I would do almost anything for a cigarette now Somewhat agree ☐

9. Smoking would make me less depressed Somewhat agree ☐

10. I am going to smoke as soon as possible Agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112450001762
----------------	----------------

Analyte	HPMA
---------	------

Sample type	URINE
-------------	-------

Result	835
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112450001762
----------------	----------------

Analyte	CEMA
---------	------

Sample type	URINE
-------------	-------

Result	100
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112450001762
----------------	----------------

Analyte	HBMA
---------	------

Sample type	URINE
-------------	-------

Result	298
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112460002075
----------------	----------------

Analyte	NNAL
---------	------

Sample type	URINE
-------------	-------

Result	416
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112460002075
----------------	----------------

Analyte	NNN
---------	-----

Sample type	URINE
-------------	-------

Result	9.45
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112470001035
----------------	----------------

Analyte	HEMA
---------	------

Sample type	URINE
-------------	-------

Result	6.35
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-05
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000199
Analyte	COT
Sample type	URINE
Result	1760
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000199
----------------	----------------

Analyte	COT-GLUC
---------	----------

Sample type	URINE
-------------	-------

Result	3180
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000199
----------------	----------------

Analyte	NIC
---------	-----

Sample type	URINE
-------------	-------

Result	392
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000199
----------------	----------------

Analyte	NIC-GLUC
---------	----------

Sample type	URINE
-------------	-------

Result	353
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000199
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	URINE
-------------	-------

Result	2910
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000199
----------------	----------------

Analyte	THCOT-GLUC
---------	------------

Sample type	URINE
-------------	-------

Result	1410
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112490001037
----------------	----------------

Analyte	3-OH BAP
---------	----------

Sample type	URINE
-------------	-------

Result	141
--------	-----

Result Unit	FG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112510001147
----------------	----------------

Analyte	1-NA
---------	------

Sample type	URINE
-------------	-------

Result	75.2
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112510001147
----------------	----------------

Analyte	2-NA
---------	------

Sample type	URINE
-------------	-------

Result	21.6
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112510001147
----------------	----------------

Analyte	4-ABP
---------	-------

Sample type	URINE
-------------	-------

Result	15.0
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112510001147
----------------	----------------

Analyte	O-TOL
---------	-------

Sample type	URINE
-------------	-------

Result	83.3
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:44

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112530000316
----------------	----------------

Analyte	11-DTXB2
---------	----------

Sample type	URINE
-------------	-------

Result	189
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-11
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:42

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112540000316
----------------	----------------

Analyte	IPF2A-III
---------	-----------

Sample type	URINE
-------------	-------

Result	151
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-12
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115190001464
----------------	----------------

Analyte	1-OHP
---------	-------

Sample type	URINE
-------------	-------

Result	154
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115170003461
----------------	----------------

Analyte	SBMA
---------	------

Sample type	URINE
-------------	-------

Result	1.09
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115170003461
----------------	----------------

Analyte	SPMA
---------	------

Sample type	URINE
-------------	-------

Result	2.75
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115180001464
----------------	----------------

Analyte	MHBMA
---------	-------

Sample type	URINE
-------------	-------

Result	2.79
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	
--------------	--

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:43

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115160001037
----------------	----------------

Analyte	CREATININE
---------	------------

Sample type	URINE
-------------	-------

Result	43.0
--------	------

Result Unit	MG/DL
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Date of Visit

28 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Randomization number (4 digits)	1049
---------------------------------	------

Allocation Arm	SA <input checked="" type="radio"/>
----------------	-------------------------------------

Cigarette Consumption	10 – 19 conventional menthol cigarettesper day <input checked="" type="radio"/>
-----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment No ☒

Time of assessment 08:54
hour:min 24-hour clock

Pulse rate 71
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 129
mmHg

Blood Pressure (diastolic) 75
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hcoleman1) 18 Jun 2015 21:00:56

Generated On: 20 Jul 2016 15:37:47

Was the Gas Transfer performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

Position

SITTING

Time of assessment

DLCO value

KCO value

DLCO/VA value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hcoleman1) 18 Jun 2015 21:00:57

Generated On: 20 Jul 2016 15:37:47

Were the Lung Volume Measurements performed?

No ☐

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

Position

SITTING

Time of assessment

VC value

TLC value

IC value

FRC value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:00:57

Generated On: 20 Jul 2016 15:37:47

Was the Spirometry with a short-acting bronchodilator performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY WERE NOT RESULTED

Category

With short-acting bronchodilator ☒

Position

SITTING

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Best measured FVC value

Percent of predicted FVC value

Best measured FEV1 value

Predicted FEV1 value

Percent of predicted FEV1 value

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:00:57

Generated On: 20 Jul 2016 15:37:47

Calculated ratio between FEV1/FVC

MEF 25/75 value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:22:46

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	20:45
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	20:45
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	05:32
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	20:45
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hfarmer1) 27 Mar 2015 14:22:46

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?	Yes <input checked="" type="radio"/>
--	--------------------------------------

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	05:32
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:52
---	-------

Result(ppm)	28
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	12:06
---	-------

Result(ppm)	51
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:11
---	-------

Result(ppm)	52
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	20:25
---	-------

Result(ppm)	48
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 27 Mar 2015 14:22:45

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

28 FEB 2014

05:32

trans-3'-hydroxyc
otinine

28 FEB 2014

05:32

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 27 Mar 2015 14:22:46

Generated On: 20 Jul 2016 15:37:47

Time of caffeine tablet intake	10:50
	hour:min 24-hour clock

Sample collection Not Done	False
----------------------------	-------

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
28 FEB 2014	16:45	Caffeine
28 FEB 2014	16:45	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,
sICAM-1, HbA1c, Apo A1, Apo B**

Data signed: (hfarmer1) 27 Mar 2015 14:22:46

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	05:32
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Start Date	28 FEB 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	06:32 hour:min 24-hour clock
------------	---------------------------------

End Date	01 MAR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	06:02 hour:min 24-hour clock
----------	---------------------------------

Volume	1973 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Were samples for 24h collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

14

How many back up tubes were collected?

13

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 28
DD/MMM/YYYY

Time of assessment

05:57
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Slight ☐

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? Slight ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 28
DD/MMM/YYYY

Time of assessment

05:56
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

05:32
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

05:32
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Was a Bio-banking sample for nasal epithelial
collection/buccal collection taken?

Yes ☒

Time of Buccal Collection

17:23
hour:min 24-hour clock

Time of Nasal Epithelial Collection

17:21
hour:min 24-hour clock

Was the subject fasting for at least 30 minutes at time of
sample collection?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	157
Reported Numeric Result	157
Reference Range low	44
Reference Range high	249
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
--------------	-----------------

Lab Test ID	RCT142
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	91
Reported Numeric Result	91
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W592792

Actual Collection Date 2014 02 28

Actual Collection Time 05:32

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48


Generated On: 20 Jul 2016 15:37:47

Lab Test Name

CHOLESTEROL (HIGH
PERFORMANCE)

Test ID

Test Status

Done 

Reported Text Result

168

Reported Numeric Result

168

Reference Range low

128

Reference Range high

236

Range Units

MG/DL

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.8
Reported Numeric Result	0.8
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT12
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.4
Reported Numeric Result	7.4
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT13
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1407
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	66
Reported Numeric Result	66
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1408
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	129
Reported Numeric Result	129
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT15
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	141
Reported Numeric Result	141
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W592792

Actual Collection Date 2014 02 28

Actual Collection Time 05:32

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.4
Reported Numeric Result	4.4
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT29
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT3
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	19
Reported Numeric Result	19
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT392
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	CREATININE (RATE BLANKED)
---------------	---------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	1.0
----------------------	-----

Reported Numeric Result	1.0
-------------------------	-----

Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT4
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	16
Reported Numeric Result	16
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT5
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	18
Reported Numeric Result	18
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT6
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	13
Reported Numeric Result	13
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT10
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.75
Reported Numeric Result	0.75
Reference Range low	0.12
Reference Range high	0.92
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT100
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	31
Reported Numeric Result	31
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT102
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT11
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.31
Reported Numeric Result	0.31
Reference Range low	0.00
Reference Range high	0.57
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT12
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.09
Reported Numeric Result	0.09
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT13
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	258
Reported Numeric Result	258
Reference Range low	140
Reference Range high	400
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT15
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	57.7
Reported Numeric Result	57.7
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT16
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	32.5
Reported Numeric Result	32.5
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT17
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	6.4
Reported Numeric Result	6.4
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W592792

Actual Collection Date 2014 02 28

Actual Collection Time 05:32

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT18

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	2.7
Reported Numeric Result	2.7
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT19
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.8
Reported Numeric Result	0.8
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT2
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	57
Reported Numeric Result	57
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High Telephone ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT3
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.3
Reported Numeric Result	6.3
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT4
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	91
Reported Numeric Result	91
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT40
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	19.2
Reported Numeric Result	19.2
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High Telephone ☒

Clinically Significant?

No ☒

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT7
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	11.78
Reported Numeric Result	11.78
Reference Range low	3.80
Reference Range high	10.70
Range Units	X10 ³ /UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT71
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48


Generated On: 20 Jul 2016 15:37:47

Lab Test Name

RBC MORPHOLOGY 1

Test ID

Test Status

Done 

Reported Text Result

NORMOCYTIC

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT8
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.80
Reported Numeric Result	6.80
Reference Range low	1.96
Reference Range high	7.23
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT9
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	3.83
Reported Numeric Result	3.83
Reference Range low	0.91
Reference Range high	4.28
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT10
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48


Generated On: 20 Jul 2016 15:37:47

Lab Test Name

UR NITRITE

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT2
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.017
Reported Numeric Result	1.017
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT3
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48


Generated On: 20 Jul 2016 15:37:47

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48


Generated On: 20 Jul 2016 15:37:47

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT5
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48


Generated On: 20 Jul 2016 15:37:47

Lab Test Name

UR GLUCOSE

Test ID

Test Status

Done 

Reported Text Result

NORMAL

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

Lab Test Name

UR BILIRUBIN

Test ID

Test Status

Done ☒

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:22:48

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCRL
--------------	---------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	9.46
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	24(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	24RHCRL
--------------	---------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	6.56
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	25-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	25HCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	4.70
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	27-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	27HCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	11.60
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	4B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	4BHCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	10.66
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	5A,6A-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5A6AECNL
--------------	----------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.46
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	5B,6B-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5B6BECNL
--------------	----------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	26.83
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	6A-HYDROXY-5A-CHOLESTAN OL
---------	-------------------------------

Analyte code	6AH5ACNL
--------------	----------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	13.70
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	7-KETOCHOLESTEROL
---------	-------------------

Analyte code	7KCRL
--------------	-------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	15.43
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	7A-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7AHCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	13.46
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	7B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7BHCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.86
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 15:37:47

Sample Accession number	3259279239
-------------------------	------------

Analyte	CHOLESTEROL
---------	-------------

Analyte code	CHOL
--------------	------

Result	
--------	--

Result Unit	MG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	0.50
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115150001330
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	.
--------	---

Result Unit	%
-------------	---

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115150001331
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-28
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Date of Birth

(b) (6)

Date of assessment

2014 FEB 28

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:04

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

A lot ☒

2. Did cigarettes taste good?

Moderately ☒

3. Did you enjoy the sensation in your throat and chest?

Moderately ☒

4. Did smoking calm you down?

A lot ☒

5. Did smoking make you feel more awake?

Moderately ☒

6. Did smoking make you feel less irritable?

A lot ☒

7. Did smoking help you concentrate?

A lot ☒

8. Did smoking reduce your hunger for food?

Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

9. Did smoking make you dizzy? Not at all ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a
cigarette? A lot ☐

12. Did you enjoy smoking? A lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done

Date of assessment	28 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:51 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input checked="" type="radio"/>
--	---

If you agree or strongly agree, please describe :

2. You enjoy smoking with the device as much as without it.	Disagree <input checked="" type="radio"/>
---	---

If you disagree or strongly disagree, please describe :	IT WAS MUCH EASIER NOT HAVING A CORD ATTACHED.
---	---

3. The taste of the conventional cigarettes/products is different with the device.	Agree <input checked="" type="radio"/>
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

If you agree or strongly agree, please describe :

IT MAKES IT TASTE LIKE
SECOND HAND SMOKE.

4. The device is easy to use.

Neither agree nor disagree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Neither agree nor disagree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 FEB 28
Time of assessment hour:min 24-hour clock	20:03
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Strongly agree <input checked="" type="radio"/>
3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
4. I could control things better right now if I could smoke	Strongly agree <input checked="" type="radio"/>
5. All I want right now is a cigarette	Strongly agree <input checked="" type="radio"/>
6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:22:47

Generated On: 20 Jul 2016 15:37:47

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Strongly agree ☐

9. Smoking would make me less depressed Strongly agree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1150
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done ☒

Reported Text Result

4.7

Reported Numeric Result

4.7

Reference Range low

Reference Range high

<6.5

Range Units

%

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1150
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16


Generated On: 20 Jul 2016 15:37:47

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done 

Reported Text Result

46

Reported Numeric Result

46

Reference Range low

30

Reference Range high

63

Range Units

MG/DL

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1150
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.063
Reported Numeric Result	0.063
Reference Range low	
Reference Range high	<=0.287
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1150
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	APOLIPOPROTEIN A1, RAND
---------------	-------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	135
----------------------	-----

Reported Numeric Result	135
-------------------------	-----

Reference Range low	110
---------------------	-----

Reference Range high	205
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1150
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	82
Reported Numeric Result	82
Reference Range low	55
Reference Range high	140
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1150
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	TEST CANCELED; HCT>55%
--------------------	------------------------

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16


Generated On: 20 Jul 2016 15:37:47

Lab Test Name

FIBRINOGEN

Test ID

Test Status

Cancelled 

Reported Text Result

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

MG/DL

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1150
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.93
Reported Numeric Result	7.93
Reference Range low	3.70
Reference Range high	13.90
Range Units	UMOL/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1150
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	316.7
Reported Numeric Result	316.7
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1150
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592792
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	05:32
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	99
----------------------	----

Reported Numeric Result	99
-------------------------	----

Reference Range low	66
---------------------	----

Reference Range high	147
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:23:16

Generated On: 20 Jul 2016 15:37:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112450001773
----------------	----------------

Analyte	HPMA
---------	------

Sample type	URINE
-------------	-------

Result	1620
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112450001773
----------------	----------------

Analyte	CEMA
---------	------

Sample type	URINE
-------------	-------

Result	212
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112450001773
----------------	----------------

Analyte	HBMA
---------	------

Sample type	URINE
-------------	-------

Result	574
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112460002104
----------------	----------------

Analyte	NNAL
---------	------

Sample type	URINE
-------------	-------

Result	629
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112460002104
----------------	----------------

Analyte	NNN
---------	-----

Sample type	URINE
-------------	-------

Result	15.5
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112470001048
----------------	----------------

Analyte	HEMA
---------	------

Sample type	URINE
-------------	-------

Result	9.15
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-05
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000201
----------------	----------------

Analyte	COT
---------	-----

Sample type	URINE
-------------	-------

Result	2090
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000201
Analyte	COT-GLUC
Sample type	URINE
Result	8140
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-28
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000201
Analyte	NIC
Sample type	URINE
Result	1180
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-28
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine Start Day	0
-----------------	---

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000201
----------------	----------------

Analyte	NIC-GLUC
---------	----------

Sample type	URINE
-------------	-------

Result	1420
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000201
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	URINE
-------------	-------

Result	6400
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112550000201
----------------	----------------

Analyte	THCOT-GLUC
---------	------------

Sample type	URINE
-------------	-------

Result	4250
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine Start Day	0
-----------------	---

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112490001048
----------------	----------------

Analyte	3-OH BAP
---------	----------

Sample type	URINE
-------------	-------

Result	274
--------	-----

Result Unit	FG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 15:37:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112500000286
----------------	----------------

Analyte	CAFFEINE
---------	----------

Sample type	PLASMA
-------------	--------

Result	535
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 15:37:47

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112500000286
----------------	----------------

Analyte	PARAXANTHINE
---------	--------------

Sample type	PLASMA
-------------	--------

Result	952
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 15:37:47

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112510001158
Analyte	1-NA
Sample type	URINE
Result	130
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112510001158
----------------	----------------

Analyte	2-NA
---------	------

Sample type	URINE
-------------	-------

Result	42.5
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112510001158
Analyte	4-ABP
Sample type	URINE
Result	20.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112510001158
Analyte	O-TOL
Sample type	URINE
Result	155
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112530000318
----------------	----------------

Analyte	11-DTXB2
---------	----------

Sample type	URINE
-------------	-------

Result	566
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-11
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112540000318
----------------	----------------

Analyte	IPF2A-III
---------	-----------

Sample type	URINE
-------------	-------

Result	306
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-12
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05113320000061
----------------	----------------

Analyte	AMES
---------	------

Sample type	URINE
-------------	-------

Result	27.4
--------	------

Result Unit	REV/ML
-------------	--------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	COUNT
------------------	-------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-15
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115190001466
----------------	----------------

Analyte	1-OHP
---------	-------

Sample type	URINE
-------------	-------

Result	269
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115170002931
Analyte	SBMA
Sample type	URINE
Result	2.10
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115170002931
----------------	----------------

Analyte	SPMA
---------	------

Sample type	URINE
-------------	-------

Result	3.34
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115180001466
----------------	----------------

Analyte	MHBMA
---------	-------

Sample type	URINE
-------------	-------

Result	5.49
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115160001048
----------------	----------------

Analyte	CREATININE
---------	------------

Sample type	URINE
-------------	-------

Result	113
--------	-----

Result Unit	MG/DL
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112440000181
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	335
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112440000181
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	24.7
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112520000286
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	278
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112520000286
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	125
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:19

Generated On: 20 Jul 2016 15:37:47

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Date of Visit

01 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

10:43
hour:min 24-hour clock

Pulse rate

69
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

114
mmHg

Blood Pressure (diastolic)

68
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	21:00
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	21:00
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:23:20

Generated On: 20 Jul 2016 15:37:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 MAR 2014
---------------------	-------------

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	21:00
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:58
---	-------

Result(ppm)	21
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:24
---	-------

Result(ppm)	15
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:42
---	-------

Result(ppm)	14
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	20:58
---	-------

Result(ppm)	6
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Start Time	06:02
	hour:min 24-hour clock

End Date	02 MAR 2014
	DD/MMM/YYYY

End Time	23:23
	hour:min 24-hour clock

Volume	<hr/>
--------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Were samples for 24h collected?

No ☒

If No, please specify the reason:

SUBJECT EARLY TERMED
FROM UNIT

How many primary tubes were collected? _____

How many back up tubes were collected? _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 01
DD/MMM/YYYY

Time of assessment

06:20
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 01
DD/MMM/YYYY

Time of assessment

06:19
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05115150001332
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	2.70
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	20
---------------------------	----

Day of Visit	1
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 MAR 01
DD/MMM/YYYY	
Time of assessment	20:07
hour:min 24-hour clock	
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Strongly agree <input checked="" type="radio"/>
3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
4. I could control things better right now if I could smoke	Strongly agree <input checked="" type="radio"/>
5. All I want right now is a cigarette	Strongly agree <input checked="" type="radio"/>
6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:23:21

Generated On: 20 Jul 2016 15:37:47

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Strongly agree ☐

9. Smoking would make me less depressed Strongly agree ☐

10. I am going to smoke as soon as possible Somewhat disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112440000182
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	93.0
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	1
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Sample Barcode	05112440000182
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	BLQ<(0.200)
--------	-------------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	1
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hcoleman1) 18 Jun 2015 21:00:57

Generated On: 20 Jul 2016 15:37:47

Date of Visit	02 MAR 2014 DD/MMM/YYYY
---------------	----------------------------

Discharge Time	00:38 hour:min 24-hour clock
----------------	---------------------------------

Is the subject continuing in the ambulatory period?	No <input checked="" type="radio"/>
---	-------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:31
----------------------	-------

Time of butt return	06:38
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:26
----------------------	-------

Time of butt return	07:33
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:18
----------------------	-------

Time of butt return	08:26
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:36
----------------------	-------

Time of butt return	09:43
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:37
----------------------	-------

Time of butt return	10:45
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:32
----------------------	-------

Time of butt return	11:40
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:12
----------------------	-------

Time of butt return	12:21
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:25
----------------------	-------

Time of butt return	13:33
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:45
----------------------	-------

Time of butt return	14:52
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:50
----------------------	-------

Time of butt return	15:57
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:34
----------------------	-------

Time of butt return	16:42
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:25
----------------------	-------

Time of butt return	17:33
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:55
----------------------	-------

Time of butt return	18:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:54
----------------------	-------

Time of butt return	19:01
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:54
----------------------	-------

Time of butt return	20:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:35
----------------------	-------

Time of butt return	20:40
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:04
----------------------	-------

Time of butt return	22:11
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:55
----------------------	-------

Time of butt return	07:02
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:51
----------------------	-------

Time of butt return	07:58
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:55
----------------------	-------

Time of butt return	09:02
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:05
----------------------	-------

Time of butt return	11:13
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:46
----------------------	-------

Time of butt return	11:55
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:24
----------------------	-------

Time of butt return	12:33
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:58
----------------------	-------

Time of butt return	13:09
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217007
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:04
----------------------	-------

Time of butt return	14:11
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217008
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:49
----------------------	-------

Time of butt return	14:56
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:40
----------------------	-------

Time of butt return	15:48
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217010
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:20
----------------------	-------

Time of butt return	16:28
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217011
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:53
----------------------	-------

Time of butt return	18:02
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217012
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:20
----------------------	-------

Time of butt return	19:29
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217013
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:09
----------------------	-------

Time of butt return	20:16
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217014
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:55
----------------------	-------

Time of butt return	21:03
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217015
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:11
----------------------	-------

Time of butt return	21:19
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	0217
----------------------------	------

SODIM file number	08DY0101COHH10217016
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hfarmer1) 27 Mar 2015 14:23:22

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 27 Mar 2015 14:23:25

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:25

Generated On: 20 Jul 2016 15:37:47

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization please explain	PRODUCT TEST
---	--------------

Time of distribution	14:46
----------------------	-------

Time of product return	<input type="text"/>
------------------------	----------------------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

Tobacco plug kit number	<input type="text"/>
-------------------------	----------------------

Tobacco plug vial number	<input type="text"/>
--------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:25

Generated On: 20 Jul 2016 15:37:47

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (1)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (2)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (3)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (4)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (5)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (6)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (7)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (8)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (9)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (10)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (11)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (12)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (13)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (14)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (15)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (16)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (17)

Generated On: 20 Jul 2016 15:37:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (18)


Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217001
-------------------	----------------------

File Status	Accepted 
-------------	--

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (19)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217002
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (20)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217003
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (21)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217004
-------------------	----------------------

File Status	Accepted 
-------------	--

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	
---------	--

Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (22)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217005
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (23)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217006
-------------------	----------------------

File Status	Accepted 
-------------	--

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	
---------	--

Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (24)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217007
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
---------	--

Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (25)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217008
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (26)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217009
-------------------	----------------------

File Status	Rejected 
-------------	--

Rejection / Error reason	BASELINE DEVIATION
--------------------------	--------------------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (27)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217010
-------------------	----------------------

File Status	Rejected 
-------------	--

Rejection / Error reason	BASELINE DEVIATION
--------------------------	--------------------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (28)


Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217011
-------------------	----------------------

File Status	Rejected 
-------------	--

Rejection / Error reason	BASELINE DEVIATION
--------------------------	--------------------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (29)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217012
-------------------	----------------------

File Status	Rejected 
-------------	--

Rejection / Error reason	BASELINE DEVIATION
--------------------------	--------------------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (30)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217013
-------------------	----------------------

File Status	Rejected 
-------------	--

Rejection / Error reason	BASELINE DEVIATION
--------------------------	--------------------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (31)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217014
-------------------	----------------------

File Status	Accepted 
-------------	--

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (32)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217015
-------------------	----------------------

File Status	Rejected 
-------------	--

Rejection / Error reason	BASELINE DEVIATION
--------------------------	--------------------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Topography files status for mCC (33)

Generated On: 20 Jul 2016 15:37:47

SODIM file number	08DY0101COHH10217016
-------------------	----------------------

File Status	Accepted 
-------------	--

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	27 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product use diary(Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:23:25

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used?

No ☒

Reason not done

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:25

Generated On: 20 Jul 2016 15:37:47

Was paper questionnaire used?

No ☐

Reason not done

Date of completion
DD/MMM/YYYY

Time of completion
hh:mm

Date the questionnaire was completed for
DD/MMM/YYYY

What tobacco/nicotine product did you use today?

How many THS 2.2 tobacco sticks did you use today?

How many CC/ roll-your-own did you smoke today?

What NRT product did you used today?

How many times did you use an inhaler today?

How many times did you use a nasal spray today?

How many gums did you use today?

How many lozenges did you use today?

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:25

Generated On: 20 Jul 2016 15:37:47

How many patches did you use today? _____

How many times did you use other NRT products today
not listed previously? _____

What other tobacco product did you used today? _____

How many times did you use chewable/smokeless
tobacco today? _____

How many cigars/cigarillos did you smoke today? _____

How many times did you smoke a pipe today? _____

How many times did you use a tobacco product today
not listed previously? _____

How many times did you use an electronic cigarette
today? _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 27 Mar 2015 14:23:25

Generated On: 20 Jul 2016 15:37:47

Was there any Adverse Event for this subject?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hcoleman1) 18 Jun 2015 21:00:57

Generated On: 20 Jul 2016 15:37:47

AE Identifier	1
---------------	---

Adverse Event	HEADACHE
---------------	----------

Start Date	27 FEB 2014
------------	-------------

DD/MMM/YYYY

End Date	27 FEB 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hcoleman1) 18 Jun 2015 21:00:57

Generated On: 20 Jul 2016 15:37:47

Action taken with study product

Not Applicable ☒

Other action taken

Outcome

Recovered or Resolved ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hcoleman1) 18 Jun 2015 21:00:57

Generated On: 20 Jul 2016 15:37:47

AE Identifier	2
---------------	---

Adverse Event	TOOTHACHE
---------------	-----------

Start Date	01 MAR 2014
------------	-------------

DD/MMM/YYYY

End Date	02 MAR 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Moderate Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	Yes <input type="radio"/>
-----------------	---------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hcoleman1) 18 Jun 2015 21:00:57

Generated On: 20 Jul 2016 15:37:47

Action taken with study product

Not Applicable ☒

Other action taken

SUBJECT WITHDREW
CONSENT

Outcome

Recovered or Resolved ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 27 Mar 2015 14:23:25

Generated On: 20 Jul 2016 15:37:47

Has the subject taken previous or concomitant
medication?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (1)

Data signed: (hfarmer1) 27 Mar 2015 14:23:25

Generated On: 20 Jul 2016 15:37:47

Brand Name	ACETAMINOPHEN
------------	---------------

Start Date DD/MMM/YYYY	01 MAR 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	02 MAR 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	3000
-------------------------	------

Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
-------------------------	--

Route	Oral Route of Administration <input checked="" type="radio"/>
-------	---

Indication	TOOTHACHE
------------	-----------

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	2
-----------	---

Other	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:25

Generated On: 20 Jul 2016 15:37:47

Brand Name	ORAJEL
------------	--------

Start Date DD/MMM/YYYY	02 MAR 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	02 MAR 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	<hr/>
-------------------------	-------

Total Daily dose - Unit	Other Dosing Unit <input checked="" type="radio"/>
-------------------------	--

Route	Topical Route of Administration <input checked="" type="radio"/>
-------	--

Indication	TOOTHACHE
------------	-----------

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	2
-----------	---

Other	<hr/>
-------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp HEMATOLOGY(19 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

19 FEB 2014

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp HEMATOLOGY(19 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	19 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	12:03
Analyte Name	WBC
Code	005025
Result	11.7
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp HEMATOLOGY(19 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	19 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	12:03
Analyte Name	RBC
Code	005033
Result	5.68
Unit	X10E6/UL
Lower limit	4.14
Upper limit	5.80
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	19 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	12:03
Analyte Name	HEMOGLOBIN
Code	005041
Result	18.0
Unit	G/DL
Lower limit	12.6
Upper limit	17.7
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

19 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:03

Analyte Name

HEMATOCRIT

Code

005058

Result

51.9

Unit

%

Lower limit

37.5

Upper limit

51.0

Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

19 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:03

Analyte Name

MCV

Code

015065

Result

91

Unit

FL

Lower limit

79

Upper limit

97

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	19 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	12:03
Analyte Name	MCH
Code	015073
Result	31.7
Unit	PG
Lower limit	26.6
Upper limit	33.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	19 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	12:03
Analyte Name	MCHC
Code	015081
Result	34.7
Unit	G/DL
Lower limit	31.5
Upper limit	35.7
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	19 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	12:03
Analyte Name	NEUTROPHILS
Code	015107
Result	66
Unit	%
Lower limit	40
Upper limit	74
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

19 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:03

Analyte Name

LYMPHS

Code

015123

Result

24

Unit

%

Lower limit

14

Upper limit

46

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

19 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:03

Analyte Name

MONOCYTES

Code

015131

Result

8

Unit

%

Lower limit

4

Upper limit

12

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	19 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	12:03
Analyte Name	EOS
Code	015149
Result	2
Unit	%
Lower limit	0
Upper limit	5
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

19 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:03

Analyte Name

BASOS

Code

015156

Result

0

Unit

%

Lower limit

0

Upper limit

3

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

19 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:03

Analyte Name

PLATELETS

Code

015172

Result

224

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

19 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:03

Analyte Name

NEUTROPHILS (ABSOLUTE)

Code

015909

Result

7.7

Unit

X10E3/UL

Lower limit

1.4

Upper limit

7.0

Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	19 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	12:03
Analyte Name	LYMPHS (ABSOLUTE)
Code	015917
Result	2.9
Unit	X10E3/UL
Lower limit	0.7
Upper limit	3.1
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

19 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:03

Analyte Name

MONOCYTES(ABSOLUTE)

Code

015925

Result

0.9

Unit

X10E3/UL

Lower limit

0.1

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	19 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	12:03
Analyte Name	EOS (ABSOLUTE)
Code	015933
Result	0.2
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.4
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

19 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

12:03

Analyte Name

BASO (ABSOLUTE)

Code

015941

Result

0.0

Unit

X10E3/UL

Lower limit

0.0

Upper limit

0.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 27 Mar 2015 14:23:26

Generated On: 20 Jul 2016 15:37:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05057100060

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1150

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:23:27

Generated On: 20 Jul 2016 15:37:47

Date of Sample Collection
DD/MMM/YYYY

Was the subject
fasting for at
least 10 hours
at time of
sample
collection?

19 FEB 2014

No

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Form: End of study

Data signed: (hcoleman1) 18 Jun 2015 21:00:55

Generated On: 20 Jul 2016 15:37:47

End of study date	30 MAR 2014 DD/MMM/YYYY
-------------------	----------------------------

Has the subject completed the study ?	No <input checked="" type="radio"/>
---------------------------------------	-------------------------------------

If No, please specify the reason:	Withdrawal by Subject <input checked="" type="radio"/>
-----------------------------------	--

Details:	THE SUBJECT DISCONTINUED FROM CRU DUE TO TOOTHACHE PAIN.
----------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Form: Consent Withdrawal

Data signed: (hfarmer1) 27 Mar 2015 14:22:13

Generated On: 20 Jul 2016 15:37:47

Did the subject withdraw it's consent to the biobanking
for BoExp and risk markers?

No ☒

Date of withdrawal of consent for biobanking for BoEXP
and risk markers

Did the subject withdraw it's consent to the
transcriptomics analysis?

No ☒

Date of withdrawal of consent for transcriptomics
analysis

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1150**

Form: Withdrawal

Data signed: (hcoleman1) 18 Jun 2015 21:00:55

Generated On: 20 Jul 2016 15:37:47

Date of withdrawal	02 MAR 2014 DD/MMM/YYYY
--------------------	-------------------------

Did the subject withdraw it's consent from the main study?	Yes <input checked="" type="radio"/>
--	--------------------------------------

If available, please provide details	SUBJECT LEFT VOLUNTARY DUE TO TOOTH PAIN
--------------------------------------	---

Did the subject withdraw from the Protected Health Information (PHI)?	No <input type="radio"/>
---	--------------------------

Did the subject confirm that samples collected up to the time of withdrawal can be analysed?	Yes <input checked="" type="radio"/>
--	--------------------------------------
