

Subject Case Report Forms

2292 (Prod: Covance Clinical Development Services, Dallas, Texas)

Generated On: 20 Jul 2016 07:11:43

All time stamps listed in this document are displayed in GMT

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Form: Subject
Data signed: (alexking1) 19 Jun 2015 16:06:38
Generated On: 20 Jul 2016 07:11:43

Screening number	2292
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Site number	DAL
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Subject Status

Form: Subject Status

Data signed: (alexking1) 19 Jun 2015 16:06:39

Generated On: 20 Jul 2016 07:11:43

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

23 APR 2014
DD/MMM/YYYY

Randomization Time

15:50
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Screening

Form: Date of Visit

Data signed: (alexking1) 19 Jun 2015 16:06:43

Generated On: 20 Jul 2016 07:11:43

Date of Visit

10 APR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Additional Informed Consent
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

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

Yes ☒

Consent Date

10 APR 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

10 APR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Inclusion Criteria
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Inclusion Criteria (1)
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

Inclusion Criterion Number	1
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Inclusion Criterion	Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF.
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Result	Yes
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*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Inclusion Criteria (2)
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

Inclusion Criterion Number	2
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Inclusion Criterion	Subject is at a minimum 22 years of age(inclusive).	<input checked="" type="radio"/>
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Result	Yes	<input checked="" type="radio"/>
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*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Inclusion Criteria (3)
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

Inclusion Criterion Number	3
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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).
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Result	Yes
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*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Inclusion Criteria (4)
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

Inclusion Criterion Number	4
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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).
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Result	Yes
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*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Inclusion Criteria (5)
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

Inclusion Criterion Number	5
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Inclusion Criterion	The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire.
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Result	Yes
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*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Inclusion Criteria (6)
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

Inclusion Criterion Number	6
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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).
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Result	Yes
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*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (1)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (2)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	2
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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).
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (3)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	3
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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.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (4)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	4
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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).
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (5)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	5
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Exclusion Criterion	Subject with asthma condition (FEV1/FVC < 0.75 and reversibility in FEV1 > 12% (or > 200 mL) from pre to post-bronchodilator values).
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (6)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	6
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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.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (7)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	7
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Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m ² .
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (8)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	8
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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.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (9)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	9
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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.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (10)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	10
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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.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (11)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	12
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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.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (12)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	13
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Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (13)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (14)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	15
Exclusion Criterion	The subject has a positive urine drug test. <input checked="" type="radio"/>
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, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (15)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	16
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Exclusion Criterion	Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B or hepatitis C.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (16)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	17
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Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission.	<input checked="" type="radio"/>
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Result	No	<input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (17)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (18)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	19
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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).
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (19)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	20
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Exclusion Criterion	The subject has participated in a clinical study within 3 months prior to the Screening Visit.	<input checked="" type="radio"/>
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Result	No	<input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (20)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

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. <input checked="" type="radio"/>
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, Dallas, Texas: 2292
Folder: Screening
Form: Exclusion Criteria (21)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Exclusion Criterion Number	22
Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception <input checked="" type="radio"/>
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, Dallas, Texas: 2292
Folder: Screening
Form: Demographics
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Date of Birth	(b) (6)
Sex	Female
Race	Black or African American
Other, specify	
Ethnicity	Not Hispanic
Date the Subject signed the Informed Consent	10 APR 2014 DD/MMM/YYYY
Time the Subject signed the Informed Consent	11:29 hour:min 24-hour clock
Age(Derived)	41

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Medical History/Concomitant Disease
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

Date of collection

10 APR 2014
DD/MMM/YYYY

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

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Medical History/Concomitant Disease (1)
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

Date of collection	10 APR 2014 DD/MMM/YYYY
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Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	1
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Diagnosis Description	WEARS PRESCRIBED GLASSES FOR MYOPIA
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Onset Date DD/MMM/YYYY	UN UNK 1986
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Stop Date DD/MMM/YYYY	
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Ongoing?	True
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Medical History/Concomitant Disease (4)
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

Date of collection	10 APR 2014 DD/MMM/YYYY
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Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	2
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Diagnosis Description	TOOTHACHE
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Onset Date DD/MMM/YYYY	03 SEP 2013
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Stop Date DD/MMM/YYYY	
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Ongoing?	True
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Vital Signs<Screening/<
Data signed: (alexking1) 19 Jun 2015 16:06:43
Generated On: 20 Jul 2016 07:11:43

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 10 APR 2014
DD/MMM/YYYY

Time of assessment 12:08
hour:min 24-hour clock

Pulse rate 69
beats per minute

Respiratory rate 18
breaths per minute

Blood Pressure (systolic) 110
mmHg

Blood Pressure (diastolic) 75
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

10 APR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (1)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (2)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (3)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (4)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (5)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (6)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (7)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (8)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (9)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (10)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (11)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (12)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (13)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (14)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 2014
DD/MMM/YYYY

System Dentition ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (15)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

10 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (16)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 2014
DD/MMM/YYYY

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (17)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 2014
DD/MMM/YYYY

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (18)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 2014
DD/MMM/YYYY

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Physical Examination (19)
Data signed: (alexking1) 19 Jun 2015 16:06:42
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 2014
DD/MMM/YYYY

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Advice on the risk of smoking and debriefing
Data signed: (alexking1) 19 Jun 2015 16:06:43
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Screening
Form: Identification of Current Cigarette Brand
Data signed: (alexking1) 19 Jun 2015 16:06:43
Generated On: 20 Jul 2016 07:11:43

Date	10 APR 2014 DD/MMM/YYYY
------	----------------------------

Brand name	KOOL BLUE TRUE MENTHOL
------------	------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: THS 2.2 menthol product demonstration
Data signed: (alexking1) 19 Jun 2015 16:06:43
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Screening
Form: Smoking History
Data signed: (alexking1) 19 Jun 2015 16:06:43
Generated On: 20 Jul 2016 07:11:43

Date of Assessment

10 APR 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, Dallas, Texas: 2292
Folder: Screening
Form: Weight and Height
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Measurement(s) assessed? Yes ☒

If No, please specify the reason: _____

Date of assessment 10 APR 2014
DD/MMM/YYYY

Weight 66.8
kg

Height 166.2
cm

BMI (Derived) 24.2
kg/m2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: ECG (12-Lead Standard)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 10 APR 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 72
beats per minute

QRS Interval 85
msec

QT Interval 371
msec

QTcB Interval 408
msec

QTcF Interval 395
msec

PR Interval 123
msec

Interpretation Normal ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: ECG (12-Lead Standard)
Data signed: (alexking1) 19 Jun 2015 16:06:40
Generated On: 20 Jul 2016 07:11:43

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Spirometry (1)
Data signed: (alexking1) 19 Jun 2015 16:06:43
Generated On: 20 Jul 2016 07:11:43

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 DD/MMM/YYYY 10 APR 2014

Time of assessment 13:41

Predicted FVC value 3.84 L

Best measured FVC value 3.71 L

Percent of predicted FVC value 96 %

Best measured FEV1 value 2.82 L

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Screening

Form: Spirometry (1)

Data signed: (alexking1) 19 Jun 2015 16:06:43

Generated On: 20 Jul 2016 07:11:43

Predicted FEV1 value	3.12 L
Percent of predicted FEV1 value	90 %
Calculated ratio between FEV1/FVC	0.76
MEF 25/75 value	2.45 L/s
Interpretation	Normal <input checked="" type="radio"/>
If Abnormal, Clinical Significance	
If Not Clinically Significant or Clinically Significant, Please specify the finding(s)	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Spirometry (2)
Data signed: (alexking1) 19 Jun 2015 16:06:43
Generated On: 20 Jul 2016 07:11:43

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 DD/MMM/YYYY 10 APR 2014

Time of assessment 14:03

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 3.84 L

Best measured FVC value 3.69 L

Percent of predicted FVC value 96 %

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Screening

Form: Spirometry (2)

Data signed: (alexking1) 19 Jun 2015 16:06:43

Generated On: 20 Jul 2016 07:11:43

Best measured FEV1 value	2.93 L
Predicted FEV1 value	3.12 L
Percent of predicted FEV1 value	93 %
Calculated ratio between FEV1/FVC	0.79
MEF 25/75 value	2.82 L/s
Interpretation	Normal <input checked="" type="radio"/>
If Abnormal, Clinical Significance	
If Not Clinically Significant or Clinically Significant, Please specify the finding(s)	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Screening

Form: Chest X-Ray

Data signed: (alexking1) 19 Jun 2015 16:06:44

Generated On: 20 Jul 2016 07:11:43

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

10 APR 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Haematology
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Screening
Form: Clinical Chemistry
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Screening
Form: Urine analysis
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Screening
Form: Serology for HIV and Hepatitis B and C
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

Category	Serology <input checked="" type="radio"/>
----------	---

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

If Not Done, please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Screening

Form: Urine Drug Screen

Data signed: (alexking1) 19 Jun 2015 16:06:41

Generated On: 20 Jul 2016 07:11:43

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

If Not Done, please specify the reason: _____

Date of sample collection	10 APR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	11:55 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (alexking1) 19 Jun 2015 16:06:41

Generated On: 20 Jul 2016 07:11:43

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Screening

Form: Alcohol Test

Data signed: (alexking1) 19 Jun 2015 16:06:41

Generated On: 20 Jul 2016 07:11:43

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 10 APR 2014
DD/MMM/YYYY

Time of assessment 11:48
hour:min 24-hour clock

Result Negative ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Urine Pregnancy Test
Generated On: 20 Jul 2016 07:11:43

Category Pregnancy Testing ☒

Not Done False

If Not Done, specify reason _____

Date of Test 10 APR 2014
DD/MMM/YYYY

Time of Test 11:55
hour:min 24-hour clock

Specify result Negative ☒

If unclear, please confirm with FSH test

Specify result of FSH test _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Urine Cotinine Test
Data signed: (alexking1) 19 Jun 2015 16:06:41
Generated On: 20 Jul 2016 07:11:43

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	10 APR 2014 DD/MMM/YYYY
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Time of Sample Collection	11:55 hour:min 24-hour clock
---------------------------	---------------------------------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp CHEMISTRY(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

10 APR 2014

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp CHEMISTRY(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	GLUCOSE, SERUM
Code	001032
Result	80
Unit	MG/DL
Lower limit	65
Upper limit	99
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp CHEMISTRY(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	BUN
Code	001040
Result	6
Unit	MG/DL
Lower limit	6
Upper limit	24
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	CHOLESTEROL, TOTAL
Code	001065
Result	164
Unit	MG/DL
Lower limit	100
Upper limit	199
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	PROTEIN, TOTAL, SERUM
Code	001073
Result	7.1
Unit	G/DL
Lower limit	6.0
Upper limit	8.5
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	ALBUMIN, SERUM
Code	001081
Result	4.3
Unit	G/DL
Lower limit	3.5
Upper limit	5.5
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	BILIRUBIN, TOTAL
Code	001099
Result	0.4
Unit	MG/DL
Lower limit	0.0
Upper limit	1.2
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	ALKALINE PHOSPHATASE, S
Code	001107
Result	68
Unit	IU/L
Lower limit	39
Upper limit	117
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	LDH
Code	001115
Result	219
Unit	IU/L
Lower limit	0
Upper limit	214
Flag	High <input checked="" type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	AST (SGOT)
Code	001123
Result	26
Unit	IU/L
Lower limit	0
Upper limit	40
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	TRIGLYCERIDES
Code	001172
Result	75
Unit	MG/DL
Lower limit	0
Upper limit	149
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	POTASSIUM, SERUM
Code	001180
Result	3.9
Unit	MMOL/L
Lower limit	3.5
Upper limit	5.2
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	SODIUM, SERUM
Code	001198
Result	137
Unit	MMOL/L
Lower limit	134
Upper limit	144
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	BILIRUBIN, DIRECT
Code	001222
Result	0.10
Unit	MG/DL
Lower limit	0.00
Upper limit	0.40
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	CREATININE, SERUM
Code	001370
Result	0.59
Unit	MG/DL
Lower limit	0.57
Upper limit	1.00
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	ALT (SGPT)
Code	001545
Result	26
Unit	IU/L
Lower limit	0
Upper limit	32
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	GGT
Code	001958
Result	37
Unit	IU/L
Lower limit	0
Upper limit	60
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	HEP C VIRUS AB
Code	140683
Result	<0.1
Unit	S/CO RATIO
Lower limit	0.0
Upper limit	0.9
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (alexking1) 19 Jun 2015 16:06:44
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp SEROLOGY(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:46
Generated On: 20 Jul 2016 07:11:43

Experiment Type	SEROLOGY
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Date of Sample Collection YYYY/MM/DD	10 APR 2014
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Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp SEROLOGY(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:46
Generated On: 20 Jul 2016 07:11:43

Experiment Type	SEROLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	HIV 1/O/2 ABS, QUAL
Code	001725
Result	NON REACTIVE
Unit	
Lower limit	NON REACTIVE
Upper limit	
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp SEROLOGY(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:46
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (alexking1) 19 Jun 2015 16:06:46
Generated On: 20 Jul 2016 07:11:43

Experiment Type	SEROLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	HBSAG SCREEN
Code	006510
Result	NEGATIVE
Unit	
Lower limit	NEGATIVE
Upper limit	
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (alexking1) 19 Jun 2015 16:06:46
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (alexking1) 19 Jun 2015 16:06:46
Generated On: 20 Jul 2016 07:11:43

Experiment Type	SEROLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	HIV 1/O/2 ABS-INDEX VALUE
Code	150010
Result	<1.00
Unit	
Lower limit	<1.00
Upper limit	
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (alexking1) 19 Jun 2015 16:06:46
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp HEMATOLOGY(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

10 APR 2014

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp HEMATOLOGY(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	WBC
Code	005025
Result	7.8
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp HEMATOLOGY(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	RBC
Code	005033
Result	4.43
Unit	X10E6/UL
Lower limit	3.77
Upper limit	5.28
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	HEMOGLOBIN
Code	005041
Result	14.6
Unit	G/DL
Lower limit	11.1
Upper limit	15.9
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	HEMATOCRIT
Code	005058
Result	43.8
Unit	%
Lower limit	34.0
Upper limit	46.6
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	MCV
Code	015065
Result	99
Unit	FL
Lower limit	79
Upper limit	97
Flag	High <input checked="" type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	MCH
Code	015073
Result	33.0
Unit	PG
Lower limit	26.6
Upper limit	33.0
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	MCHC
Code	015081
Result	33.3
Unit	G/DL
Lower limit	31.5
Upper limit	35.7
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	NEUTROPHILS
Code	015107
Result	54
Unit	%
Lower limit	40
Upper limit	74
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

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Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	LYMPHS
Code	015123
Result	38
Unit	%
Lower limit	14
Upper limit	46
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	MONOCYTES
Code	015131
Result	6
Unit	%
Lower limit	4
Upper limit	12
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

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Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	EOS
Code	015149
Result	2
Unit	%
Lower limit	0
Upper limit	5
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	BASOS
Code	015156
Result	0
Unit	%
Lower limit	0
Upper limit	3
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	PLATELETS
Code	015172
Result	273
Unit	X10E3/UL
Lower limit	155
Upper limit	379
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

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Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	NEUTROPHILS (ABSOLUTE)
Code	015909
Result	4.1
Unit	X10E3/UL
Lower limit	1.4
Upper limit	7.0
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	LYMPHS (ABSOLUTE)
Code	015917
Result	3.0
Unit	X10E3/UL
Lower limit	0.7
Upper limit	3.1
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	MONOCYTES(ABSOLUTE)
Code	015925
Result	0.5
Unit	X10E3/UL
Lower limit	0.1
Upper limit	0.9
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	EOS (ABSOLUTE)
Code	015933
Result	0.2
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.4
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (18)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	13:18
Analyte Name	BASO (ABSOLUTE)
Code	015941
Result	0.0
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.2
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (18)
Data signed: (alexking1) 19 Jun 2015 16:06:47
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp URINALYSIS(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

10 APR 2014

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp URINALYSIS(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:55
Analyte Name	SPECIFIC GRAVITY
Code	013060
Result	1.010
Unit	
Lower limit	1.005
Upper limit	1.030
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp URINALYSIS(10 APR 2014)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:55
Analyte Name	PH
Code	013078
Result	6.5
Unit	
Lower limit	5.0
Upper limit	7.5
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:55
Analyte Name	GLUCOSE
Code	013086
Result	NEGATIVE
Unit	
Lower limit	NEGATIVE
Upper limit	
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:55
Analyte Name	PROTEIN
Code	013094
Result	NEGATIVE
Unit	
Lower limit	NEGATIVE/TRACE
Upper limit	
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:55
Analyte Name	OCCULT BLOOD
Code	013102
Result	NEGATIVE
Unit	
Lower limit	NEGATIVE
Upper limit	
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:55
Analyte Name	BILIRUBIN
Code	013104
Result	NEGATIVE
Unit	
Lower limit	NEGATIVE
Upper limit	
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	10 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:55
Analyte Name	NITRITE, URINE
Code	013106
Result	NEGATIVE
Unit	
Lower limit	NEGATIVE
Upper limit	
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (alexking1) 19 Jun 2015 16:06:48
Generated On: 20 Jul 2016 07:11:43

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 10096700050

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Screening
Form: FTND Questionnaire
Generated On: 20 Jul 2016 07:11:43

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

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

Date of assessment	2014 APR 10
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	14:16
	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?	Within 5 minutes <input checked="" type="radio"/>
--	---

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	Yes <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?	21-30 <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, Dallas, Texas: 2292

Folder: Screening

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

Data signed: (alexking1) 19 Jun 2015 16:06:43

Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 10 APR 2014
DD/MMM/YYYY

Time of assessment 11:45
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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Date of Visit
Data signed: (alexking1) 19 Jun 2015 16:06:51
Generated On: 20 Jul 2016 07:11:43

Date of Visit

21 APR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Inclusion Criteria
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Inclusion Criteria (2)
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Exclusion Criteria
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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 <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, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥35 kg/m2.
---------------------	---

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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
--------	----

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Exclusion Criteria (7)
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Exclusion Criteria (8)
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

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 <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, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Exclusion Criteria (10)
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Exclusion Criteria (11)
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Exclusion Criteria (12)
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

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 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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Exclusion Criteria (13)
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

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. <input 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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Exclusion Criteria (14)
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Vital Signs
Data signed: (alexking1) 19 Jun 2015 16:06:51
Generated On: 20 Jul 2016 07:11:43

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 16:02
hour:min 24-hour clock

Pulse rate 77
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 110
mmHg

Blood Pressure (diastolic) 73
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Product preference

Data signed: (alexking1) 19 Jun 2015 16:06:51

Generated On: 20 Jul 2016 07:11:43

Which Product Arm would you prefer to be randomized
to:

mCC 

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Advice on the risk of smoking and debriefing
Data signed: (alexking1) 19 Jun 2015 16:06:51
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (1)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (2)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (3)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (4)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (5)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (6)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (7)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (8)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (9)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (10)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (11)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (12)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (13)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (14)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (15)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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 APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (16)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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 APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (17)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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 APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (18)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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 APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Physical Examination (19)
Data signed: (alexking1) 19 Jun 2015 16:06:50
Generated On: 20 Jul 2016 07:11:43

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 APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Identification of Current Cigarette Brand
Data signed: (alexking1) 19 Jun 2015 16:06:51
Generated On: 20 Jul 2016 07:11:43

Brand name

KOOL BLUE TRUE MENTHOL

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: THS 2.2 menthol product test
Data signed: (alexking1) 19 Jun 2015 16:06:51
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Smoking History
Data signed: (alexking1) 19 Jun 2015 16:06:51
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Weight
Data signed: (alexking1) 19 Jun 2015 16:06:51
Generated On: 20 Jul 2016 07:11:43

Measurement(s) assessed? Yes ☒

If No, please specify the reason: _____

Time of assessment 15:26
hour:min 24-hour clock

Weight 65.9
kg

Waist circumference 82
cm

BMI 23.9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

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

If Not Done, please specify the reason: _____

Time of sample collection	16:05
	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, Dallas, Texas: 2292

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (alexking1) 19 Jun 2015 16:06:49

Generated On: 20 Jul 2016 07:11:43

Drug type	Result
Opiates	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Alcohol Test
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 15:30
hour:min 24-hour clock

Result Negative ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: Urine Pregnancy Test
Generated On: 20 Jul 2016 07:11:43

Not Done False

If Not Done, specify reason _____

Time of Test 16:05
hour:min 24-hour clock

Specify result Negative ☒

If unclear, please confirm with FSH test

Specify result of FSH test _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Admission (Day -2)
Form: CO Breath Test
Data signed: (alexking1) 19 Jun 2015 16:06:49
Generated On: 20 Jul 2016 07:11:43

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	16:28
	hour:min 24-hour clock

Result	23
	ppm

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Admission (Day -2)

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

Data signed: (alexking1) 19 Jun 2015 16:06:51

Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 21 APR 2014
DD/MMM/YYYY

Time of assessment 15:48
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, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Date of Visit
Data signed: (alexking1) 19 Jun 2015 16:06:53
Generated On: 20 Jul 2016 07:11:43

Date of Visit

22 APR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Vital Signs
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

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 10:07
hour:min 24-hour clock

Pulse rate 80
beats per minute

Respiratory rate 18
breaths per minute

Blood Pressure (systolic) 107
mmHg

Blood Pressure (diastolic) 71
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (alexking1) 19 Jun 2015 16:06:51

Generated On: 20 Jul 2016 07:11:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	22 APR 2014
---------------------	-------------

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	20:38
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (alexking1) 19 Jun 2015 16:06:51

Generated On: 20 Jul 2016 07:11:43

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	06:23
---	-------

Result(ppm)	8
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (alexking1) 19 Jun 2015 16:06:51

Generated On: 20 Jul 2016 07:11:43

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	12:28
---	-------

Result(ppm)	16
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (alexking1) 19 Jun 2015 16:06:51

Generated On: 20 Jul 2016 07:11:43

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	16:44
---	-------

Result(ppm)	16
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (alexking1) 19 Jun 2015 16:06:51

Generated On: 20 Jul 2016 07:11:43

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	20:28
---	-------

Result(ppm)	19
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: 4 hour urine collection
Data signed: (alexking1) 19 Jun 2015 16:06:53
Generated On: 20 Jul 2016 07:11:43

Start Time	09:48 hour:min 24-hour clock
------------	---------------------------------

End Time	13:52 hour:min 24-hour clock
----------	---------------------------------

Volume	208 mL
--------	-----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Sample Urine Collection (4 Hour collection)
Data signed: (alexking1) 19 Jun 2015 16:06:53
Generated On: 20 Jul 2016 07:11:43

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? 8

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (alexking1) 19 Jun 2015 16:06:54

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115150005105
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	5.00
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-APR-22
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (alexking1) 19 Jun 2015 16:06:54

Generated On: 20 Jul 2016 07:11:43

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Date of Birth

(b) (6)

Date of assessment

2014 APR 22
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:04
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Extremely ☒

2. Did cigarettes taste good?

Extremely ☒

3. Did you enjoy the sensation in your throat and chest?

A lot ☒

4. Did smoking calm you down?

Extremely ☒

5. Did smoking make you feel more awake?

Extremely ☒

6. Did smoking make you feel less irritable?

Extremely ☒

7. Did smoking help you concentrate?

A lot ☒

8. Did smoking reduce your hunger for food?

Little ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

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? Not at all ☐

12. Did you enjoy smoking? Extremely ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Behavioral Risk Factor Surveillance System Questionnaire
Data signed: (alexking1) 19 Jun 2015 16:06:51
Generated On: 20 Jul 2016 07:11:43

Type	BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	22 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:10 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?	Within the past month (less than 1 month ago) <input type="radio"/>
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Behavioral Risk Factor Surveillance System Questionnaire
Data signed: (alexking1) 19 Jun 2015 16:06:51
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	22 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:17 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?	No <input checked="" type="radio"/>
--	-------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	33 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, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

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 0 Years

Months 0 Months

Days 0 Days

7. What brand of cigarettes/hand-rolled tobacco did you KOOL BLUE SHORT BOX
predominantly smoke in the last 12 months of smoking?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	22 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:17 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?	No <input checked="" type="radio"/>
--	-------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	33 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, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

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 0 Years

Months 0 Months

Days 0 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

Time Currently (last 3 months) ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day? _____

Manufactured Cigarettes 20
per day

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day? _____

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

8. On average, how many cigars do/did you smoke per day? _____

Cigars
per day _____

8. On average, how many pipes do/did you smoke per day? _____

Pipes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (2)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	22 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:17 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?	No <input checked="" type="radio"/>
--	-------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	33 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, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (2)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

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 _____ 0 Years

Months _____ 0 Months

Days _____ 0 Days

7. What brand of cigarettes/hand-rolled tobacco did you KOOL BLUE SHORT BOX
predominantly smoke in the last 12 months of smoking?

Time _____ 1 year ago ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day? _____

Manufactured Cigarettes _____ 20
per day

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day? _____

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (2)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

8. On average, how many cigars do/did you smoke per day? _____

Cigars
per day _____

8. On average, how many pipes do/did you smoke per day? _____

Pipes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (3)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	22 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:17 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?	No <input checked="" type="radio"/>
--	-------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	33 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, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (3)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

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 0 Years

Months 0 Months

Days 0 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? KOOL BLUE SHORT BOX

Time 5 years ago 

8. On average, how many Manufactured cigarettes do/did you smoke per day?

Manufactured Cigarettes per day 20

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

Hand-rolled Cigarettes per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (3)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

8. On average, how many cigars do/did you smoke per day? _____

Cigars
per day _____

8. On average, how many pipes do/did you smoke per day? _____

Pipes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (4)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	22 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:17 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?	No <input checked="" type="radio"/>
--	-------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	33 Years
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5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (4)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

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 0 Years

Months 0 Months

Days 0 Days

7. What brand of cigarettes/hand-rolled tobacco did you KOOL BLUE SHORT BOX
predominantly smoke in the last 12 months of smoking?

Time 10 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? _____

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (4)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

8. On average, how many cigars do/did you smoke per day? _____

Cigars
per day _____

8. On average, how many pipes do/did you smoke per day? _____

Pipes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (5)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
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Date of assessment	22 APR 2014 DD/MMM/YYYY
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Time of assessment	20:17 hour:min 24-hour clock
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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?	No <input checked="" type="radio"/>
--	-------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	33 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, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (5)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

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 0 Years

Months 0 Months

Days 0 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

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? _____

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (5)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

8. On average, how many cigars do/did you smoke per day? _____

Cigars
per day _____

8. On average, how many pipes do/did you smoke per day? _____

Pipes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (6)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	22 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:17 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?	No <input checked="" type="radio"/>
--	-------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	33 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, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (6)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

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 _____ 0 Years

Months _____ 0 Months

Days _____ 0 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? KOOL BLUE SHORT BOX

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? _____

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (6)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

8. On average, how many cigars do/did you smoke per day? _____

Cigars
per day _____

8. On average, how many pipes do/did you smoke per day? _____

Pipes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (7)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
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Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
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Date of assessment	22 APR 2014 DD/MMM/YYYY
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Time of assessment	20:17 hour:min 24-hour clock
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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?	No <input checked="" type="radio"/>
--	-------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	33 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (7)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

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 _____ 0 Years

Months _____ 0 Months

Days _____ 0 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? KOOL BLUE SHORT BOX

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? _____

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (7)
Data signed: (alexking1) 19 Jun 2015 16:06:52
Generated On: 20 Jul 2016 07:11:43

8. On average, how many cigars do/did you smoke per day? _____

Cigars
per day _____

8. On average, how many pipes do/did you smoke per day? _____

Pipes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Supplemental Questions
Data signed: (alexking1) 19 Jun 2015 16:06:53
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 22 APR 2014
DD/MMM/YYYY

Time of assessment 20:20

1. How long it takes for the subject to complete the SQ 3 minutes

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Supplemental Questions (1)
Data signed: (alexking1) 19 Jun 2015 16:06:53
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 22 APR 2014
DD/MMM/YYYY

Time of assessment 20:20

1. How long it takes for the subject to complete the SQ 3 minutes

Question 2. Did the SQ capture your smoking behavior completely? ☒

Answer Yes ☒

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Supplemental Questions (2)
Data signed: (alexking1) 19 Jun 2015 16:06:53
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 22 APR 2014
DD/MMM/YYYY

Time of assessment 20:20

1. How long it takes for the subject to complete the SQ 3 minutes

Question 3. Did the SQ capture your smoking behavior correctly? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Supplemental Questions (3)
Data signed: (alexking1) 19 Jun 2015 16:06:53
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 22 APR 2014
DD/MMM/YYYY

Time of assessment 20:20

1. How long it takes for the subject to complete the SQ 3 minutes

Question 4. Did the SQ capture your smoking history completely? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Supplemental Questions (4)
Data signed: (alexking1) 19 Jun 2015 16:06:53
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 22 APR 2014
DD/MMM/YYYY

Time of assessment 20:20

1. How long it takes for the subject to complete the SQ 3 minutes

Question 5. Did the SQ capture your smoking history correctly? ☒

Answer Yes ☒

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Supplemental Questions (5)
Data signed: (alexking1) 19 Jun 2015 16:06:53
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 22 APR 2014
DD/MMM/YYYY

Time of assessment 20:20

1. How long it takes for the subject to complete the SQ 3 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Supplemental Questions (6)
Data signed: (alexking1) 19 Jun 2015 16:06:53
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 22 APR 2014
DD/MMM/YYYY

Time of assessment 20:20

1. How long it takes for the subject to complete the SQ 3 minutes

Question 7. Was the SQ easy to use? ☒

Answer Yes ☒

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Questionnaire on smoking urges (QSU)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 APR 22
DD/MMM/YYYY	
Time of assessment	20:02
hour:min 24-hour clock	
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Strongly agree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Strongly 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	Strongly agree <input type="radio"/>
7. A cigarette would taste good now	Agree <input type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Questionnaire on smoking urges (QSU)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

8. I would do almost anything for a cigarette now Agree ☐

9. Smoking would make me less depressed Do not agree or disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112450005828
Analyte	HPMA
Sample type	URINE
Result	792
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112450005828
Analyte	CEMA
Sample type	URINE
Result	132
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
---------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112450005828
Analyte	HBMA
Sample type	URINE
Result	280
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112460005991
Analyte	NNAL
Sample type	URINE
Result	283
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112460005991
Analyte	NNN
Sample type	URINE
Result	1.27
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (HEMA)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (HEMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112470003567
Analyte	HEMA
Sample type	URINE
Result	13.2
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (HEMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(1)

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000773
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Analyte	COT
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Sample type	URINE
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Result	2260
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-13
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Date of Collection	2014-APR-22
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Timepoint-minutes	
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(1)

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(2)

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000773
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Analyte	COT-GLUC
---------	----------

Sample type	URINE
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Result	1730
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-13
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Date of Collection	2014-APR-22
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
-----------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(3)

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000773
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Analyte	NIC
---------	-----

Sample type	URINE
-------------	-------

Result	355
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-13
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Date of Collection	2014-APR-22
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
---------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(4)

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000773
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Analyte	NIC-GLUC
---------	----------

Sample type	URINE
-------------	-------

Result	126
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	-1
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Celerion Study Number	AA99128-13
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Date of Collection	2014-APR-22
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Timepoint-minutes	
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(4)

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(5)

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000773
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Analyte	THCOT
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Sample type	URINE
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Result	8160
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-13
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Date of Collection	2014-APR-22
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Timepoint-minutes	
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000773
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Analyte	THCOT-GLUC
---------	------------

Sample type	URINE
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Result	4150
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-13
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Date of Collection	2014-APR-22
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Timepoint-minutes	
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(6)

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (3-OH BaP)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112490003567
Analyte	3-OH BAP
Sample type	URINE
Result	170
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112510003611
Analyte	1-NA
Sample type	URINE
Result	76.1
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112510003611
Analyte	2-NA
Sample type	URINE
Result	22.6
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (alexking1) 19 Jun 2015 16:06:56

Generated On: 20 Jul 2016 07:11:43

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112510003611
Analyte	4-ABP
Sample type	URINE
Result	16.8
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112510003611
Analyte	O-TOL
Sample type	URINE
Result	148
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (11-dTXb2)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112530002243
Analyte	11-DTXB2
Sample type	URINE
Result	642
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (iPF2a-III)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112540002075
Analyte	IPF2A-III
Sample type	URINE
Result	432
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:54
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (alexking1) 19 Jun 2015 16:06:56

Generated On: 20 Jul 2016 07:11:43

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115190004711
Analyte	1-OHP
Sample type	URINE
Result	328
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (alexking1) 19 Jun 2015 16:06:56

Generated On: 20 Jul 2016 07:11:43

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115170004929
Analyte	SBMA
Sample type	URINE
Result	7.72
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (alexking1) 19 Jun 2015 16:06:55

Generated On: 20 Jul 2016 07:11:43

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115170004929
Analyte	SPMA
Sample type	URINE
Result	2.67
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (MHBMA)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115180000705
Analyte	MHBMA
Sample type	URINE
Result	1.22
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:55
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Creatinine)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115160003039
Analyte	CREATININE
Sample type	URINE
Result	106
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-APR-22
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Date of Visit
Data signed: (alexking1) 19 Jun 2015 16:06:58
Generated On: 20 Jul 2016 07:11:43

Date of Visit

23 APR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Randomization
Data signed: (alexking1) 19 Jun 2015 16:06:59
Generated On: 20 Jul 2016 07:11:43

Randomization number (4 digits)	4020
Allocation Arm	SA <input checked="" type="radio"/>
Cigarette Consumption	Greater than 19 conventional menthol cigarettes per day <input checked="" type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Vital Signs
Data signed: (alexking1) 19 Jun 2015 16:06:58
Generated On: 20 Jul 2016 07:11:43

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 10:11
hour:min 24-hour clock

Pulse rate 76
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 104
mmHg

Blood Pressure (diastolic) 77
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Gas Transfer
Data signed: (alexking1) 19 Jun 2015 16:06:57
Generated On: 20 Jul 2016 07:11:43

Was the Gas Transfer performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 08:25

DLCO value 16.81
ml/min/mmHg

KCO value 1.10
mmol/min/kPa/L

DLCO/VA value 1.10
mL/min/mmHg/L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

If Not Clinically Significant or Clinically Significant, Please DECREASED LUNG VOLUME
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lung Volume Measurements
Data signed: (alexking1) 19 Jun 2015 16:06:57
Generated On: 20 Jul 2016 07:11:43

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 08:34

VC value 3.94
L

TLC value 5.29
L

IC value 2.49
L

FRC value 2.80
L

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Spirometry with a short-acting bronchodilator
Data signed: (alexking1) 19 Jun 2015 16:06:57
Generated On: 20 Jul 2016 07:11:43

Was the Spirometry with a short-acting bronchodilator performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Position SITTING

Time of assessment 09:09

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 3.84 L

Best measured FVC value 3.89 L

Percent of predicted FVC value 101 %

Best measured FEV1 value 2.99 L

Predicted FEV1 value 3.12 L

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Spirometry with a short-acting bronchodilator
Data signed: (alexking1) 19 Jun 2015 16:06:57
Generated On: 20 Jul 2016 07:11:43

Percent of predicted FEV1 value	95 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	_____
-----------------------------------	-------

MEF 25/75 value	2.56 L/s
-----------------	-------------

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

If Abnormal, Clinical Significance	_____
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If Not Clinically Significant or Clinically Significant, Please specify the finding(s)	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Haematology
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Clinical Chemistry
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Urine analysis
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Plasma Nicotine Sample
Data signed: (alexking1) 19 Jun 2015 16:06:57
Generated On: 20 Jul 2016 07:11:43

Not Done	False
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If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	23 APR 2014
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Time hour:min 24-hour clock	20:55
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Plasma Cotinine Sample
Data signed: (alexking1) 19 Jun 2015 16:06:57
Generated On: 20 Jul 2016 07:11:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	23 APR 2014
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Time hour:min 24-hour clock	20:55
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: CoHb Blood Sample <D0> (1)
Data signed: (alexking1) 19 Jun 2015 16:06:57
Generated On: 20 Jul 2016 07:11:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	23 APR 2014
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Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	05:37
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: CoHb Blood Sample <D0> (2)
Data signed: (alexking1) 19 Jun 2015 16:06:57
Generated On: 20 Jul 2016 07:11:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	23 APR 2014
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Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	20:55
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterols
Data signed: (alexking1) 19 Jun 2015 16:06:57
Generated On: 20 Jul 2016 07:11:43

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	23 APR 2014
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Time hour:min 24-hour clock	05:37
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (alexking1) 19 Jun 2015 16:06:56

Generated On: 20 Jul 2016 07:11:43

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	09:18
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Result(ppm)	20
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: CO Breath Test (2)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

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	12:09
---	-------

Result(ppm)	30
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (alexking1) 19 Jun 2015 16:06:56

Generated On: 20 Jul 2016 07:11:43

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
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Actual Time of Assessment hour:min 24-hour clock	16:40
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Result(ppm)	22
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: CO Breath Test (4)
Data signed: (alexking1) 19 Jun 2015 16:06:56
Generated On: 20 Jul 2016 07:11:43

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
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Actual Time of Assessment hour:min 24-hour clock	21:01
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Result(ppm)	35
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (alexking1) 19 Jun 2015 16:06:57

Generated On: 20 Jul 2016 07:11:43

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

23 APR 2014

05:37

trans-3'-hydroxyc
otinine

23 APR 2014

05:37

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (alexking1) 19 Jun 2015 16:06:57

Generated On: 20 Jul 2016 07:11:43

Time of caffeine tablet intake	10:04
	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
23 APR 2014	16:07	Caffeine
23 APR 2014	16:07	Paraxanthine

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,
sICAM-1, HbA1c, Apo A1, Apo B**

Data signed: (alexking1) 19 Jun 2015 16:06:57

Generated On: 20 Jul 2016 07:11:43

Not Done	False
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If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	23 APR 2014
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Time hour:min 24-hour clock	05:37
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: 24 hour urine collections
Data signed: (alexking1) 19 Jun 2015 16:06:58
Generated On: 20 Jul 2016 07:11:43

Start Date	23 APR 2014 DD/MMM/YYYY
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Start Time	10:47 hour:min 24-hour clock
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End Date	24 APR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	06:17 hour:min 24-hour clock
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Volume	1625 mL
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Sample Urine Collection
Data signed: (alexking1) 19 Jun 2015 16:06:58
Generated On: 20 Jul 2016 07:11:43

Were samples for 24h 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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (alexking1) 19 Jun 2015 16:07:00
Generated On: 20 Jul 2016 07:11:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 23
DD/MMM/YYYY

Time of assessment

06:35
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?

Mild ☒

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?

Severe ☒

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (alexking1) 19 Jun 2015 16:07:00
Generated On: 20 Jul 2016 07:11:43

How have you been feeling over the past 24 hours? Moderate ☒

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Mild ☒

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? Mild ☒

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Mild ☒

8. Restless

How have you been feeling over the past 24 hours? Slight ☒

9. Impatient

How have you been feeling over the past 24 hours? Slight ☒

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (alexking1) 19 Jun 2015 16:07:00
Generated On: 20 Jul 2016 07:11:43

How have you been feeling over the past 24 hours? Slight ☒

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Cough Assessment
Data signed: (alexking1) 19 Jun 2015 16:06:59
Generated On: 20 Jul 2016 07:11:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 23
DD/MMM/YYYY

Time of assessment

06:31
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Bio-banking (Transcriptomics)
Data signed: (alexking1) 19 Jun 2015 16:06:59
Generated On: 20 Jul 2016 07:11:43

Was a Bio-banking sample for transcriptomics taken? Yes ☒

Time of Sample Collection 05:37
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Bio-banking (Biomarkers of exposure and risk markers)
Data signed: (alexking1) 19 Jun 2015 16:06:59
Generated On: 20 Jul 2016 07:11:43

Was a Bio-banking sample for biomarkers of exposure and risk markers taken? Yes ☒

Time of Sample Collection 05:37
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Bio-banking (nasal epithelial collection/buccal collection)
Data signed: (alexking1) 19 Jun 2015 16:06:59
Generated On: 20 Jul 2016 07:11:43

Was a Bio-banking sample for nasal epithelial collection/buccal collection taken? Yes ☐

Time of Buccal Collection 15:10
hour:min 24-hour clock

Time of Nasal Epithelial Collection 15:08
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (1)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X086761

Actual Collection Date 2014 04 23

Actual Collection Time 05:37

Specimen Condition _____


Battery ID RC1029

Battery Name TRIGLYCERIDES

Lab Test ID RCT19

Lab Test Name TRIGLYCERIDES (GPO)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (1)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	86
Reported Numeric Result	86
Reference Range low	45
Reference Range high	214
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (1)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (2)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X086761

Actual Collection Date 2014 04 23

Actual Collection Time 05:37

Specimen Condition _____


Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

Lab Test Name FASTING GLUCOSE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (2)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	94
Reported Numeric Result	94
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (2)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (3)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X086761

Actual Collection Date 2014 04 23

Actual Collection Time 05:37

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (3)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	150
Reported Numeric Result	150
Reference Range low	155
Reference Range high	265
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (3)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

SI Numeric Result _____

SI Reference Range Low _____

SI Reference Range High _____

SI Units _____

Reported Result Type _____

Alert Flag Low ☒

Clinically Significant? No ☒

Comment _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (4)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X086761

Actual Collection Date 2014 04 23

Actual Collection Time 05:37

Specimen Condition _____


Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

Lab Test Name TOTAL BILIRUBIN

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (4)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	0.3
Reported Numeric Result	0.3
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (4)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (5)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT12
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Lab Test Name	TOTAL PROTEIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (5)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	6.3
Reported Numeric Result	6.3
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (5)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (6)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT13
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Lab Test Name	ALBUMIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (6)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	3.4
Reported Numeric Result	3.4
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (6)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (7)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1407
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Lab Test Name	ALKALINE PHOSPHATASE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (7)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	62
Reported Numeric Result	62
Reference Range low	31
Reference Range high	106
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (7)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (8)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1408
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Lab Test Name	LDH
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (8)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	176
Reported Numeric Result	176
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (8)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (9)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT15
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Lab Test Name	SERUM SODIUM
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (9)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	138
Reported Numeric Result	138
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (9)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (10)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
------------------------	------------

Actual Collection Time	05:37
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT16
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Lab Test Name	SERUM POTASSIUM
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (10)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	3.9
Reported Numeric Result	3.9
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (10)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (11)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT29
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Lab Test Name	DIRECT BILIRUBIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (11)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	<0.1
Reported Numeric Result	
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (11)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (12)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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Lab Test Name	GGT
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (12)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	36
Reported Numeric Result	36
Reference Range low	4
Reference Range high	49
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (12)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (13)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT392
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Lab Test Name	CREATININE (RATE BLANKED)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (13)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	0.7
Reported Numeric Result	0.7
Reference Range low	0.4
Reference Range high	1.1
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (13)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (14)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT4
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Lab Test Name	ALT (SGPT)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (14)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	13
Reported Numeric Result	13
Reference Range low	6
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (14)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (15)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT5
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Lab Test Name	AST (SGOT)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (15)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	19
Reported Numeric Result	19
Reference Range low	9
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (15)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (16)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT6
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Lab Test Name	UREA NITROGEN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (16)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	10
Reported Numeric Result	10
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (16)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (17)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (17)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.35
Reported Numeric Result	0.35
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (17)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (18)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT100
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (18)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	32
Reported Numeric Result	32
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (18)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (19)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT102
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (19)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (19)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (20)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT11
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (20)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.18
Reported Numeric Result	0.18
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (20)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (21)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (21)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.02
Reported Numeric Result	0.02
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (21)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (22)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT13
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (22)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	283
Reported Numeric Result	283
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (22)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (23)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (23)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	48.0
Reported Numeric Result	48.0
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (23)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

SI Numeric Result	<hr/>
SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (24)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (24)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	42.9
Reported Numeric Result	42.9
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (24)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (25)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT17
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (25)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.7
Reported Numeric Result	5.7
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (25)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

SI Numeric Result	<hr/>
SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (26)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT18
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (26)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.0
Reported Numeric Result	3.0
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (26)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (27)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT19
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (27)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (27)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (28)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (28)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	42
Reported Numeric Result	42
Reference Range low	34
Reference Range high	48
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (28)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (29)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (29)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	RBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.3
Reported Numeric Result	4.3
Reference Range low	4.1
Reference Range high	5.6
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (29)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (30)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (30)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	97
Reported Numeric Result	97
Reference Range low	79
Reference Range high	98
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (30)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

SI Numeric Result	<hr/>
SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (31)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X086761

Actual Collection Date 2014 04 23

Actual Collection Time 05:37

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT40

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (31)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13.9
Reported Numeric Result	13.9
Reference Range low	11.6
Reference Range high	16.4
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (31)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (32)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT7
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (32)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.08
Reported Numeric Result	6.08
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (32)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (33)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT71
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (33)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	RBC MORPHOLOGY 1
Test ID	
Test Status	Done <input type="radio"/>
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (33)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (34)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X086761

Actual Collection Date 2014 04 23

Actual Collection Time 05:37

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT8

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (34)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	2.92
Reported Numeric Result	2.92
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (34)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (35)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X086761

Actual Collection Date 2014 04 23

Actual Collection Time 05:37

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (35)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.61
Reported Numeric Result	2.61
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (35)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (36)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT10
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Lab Test Name	UR NITRITE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (36)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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 _____

SI Numeric Result _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (36)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (37)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT2
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Lab Test Name	UR SPECIFIC GRAVITY
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (37)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	1.011
Reported Numeric Result	1.011
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (37)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (38)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT3
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Lab Test Name	UR PH
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (38)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (38)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (39)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
------------------------	------------

Actual Collection Time	05:37
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
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Lab Test Name	UR BLOOD
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (39)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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 _____

SI Numeric Result _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (39)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (40)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT49
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Lab Test Name	UR PROTEIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (40)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	NEGATIVE
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Reported Numeric Result	<hr/>
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Reference Range low	<hr/>
---------------------	-------

Reference Range high	<hr/>
----------------------	-------

Range Units	<hr/>
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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SI Numeric Result	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (40)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (41)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
--------------	---------

Actual Collection Date	2014 04 23
------------------------	------------

Actual Collection Time	05:37
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------


Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT5
-------------	------

Lab Test Name	UR GLUCOSE
---------------	------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (41)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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 _____

SI Numeric Result _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (41)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (42)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X086761
--------------	---------

Actual Collection Date	2014 04 23
------------------------	------------

Actual Collection Time	05:37
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
-------------	------

Lab Test Name	UR BILIRUBIN
---------------	--------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (42)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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 _____

SI Numeric Result _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (42)
Data signed: (alexking1) 19 Jun 2015 16:07:04
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (1)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
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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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (2)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
-------------------------	------------

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (3)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
-------------------------	------------

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (4)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
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Analyte	27-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	27HCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
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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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (5)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
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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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (6)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
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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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (7)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
-------------------------	------------

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (8)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
-------------------------	------------

Analyte	6A-HYDROXY-5A-CHOLESTAN OL
---------	-------------------------------

Analyte code	6AH5ACNL
--------------	----------

Result	
--------	--

Result Unit	NG/ML
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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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (9)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
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Analyte	7-KETOCHOLESTEROL
---------	-------------------

Analyte code	7KCRL
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Result	
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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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (10)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
-------------------------	------------

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (11)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
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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	
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Collection time hh:mm 24 hour clock	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Oxysterol results (12)
Generated On: 20 Jul 2016 07:11:43

Sample Accession number	3308676139
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Analyte	CHOLESTEROL
---------	-------------

Analyte code	CHOL
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Result	
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Result Unit	MG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	0.50
-------------------------------	------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_COHB (1)
Data signed: (alexking1) 19 Jun 2015 16:07:16
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115150005106
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	4.60
Result Unit	%
Lab Status	OK
Sample comment	
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-APR-23
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (alexking1) 19 Jun 2015 16:07:16

Generated On: 20 Jul 2016 07:11:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Lab_BU_COHB (2)
Data signed: (alexking1) 19 Jun 2015 16:07:16
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115150005107
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	8.60
Result Unit	%
Lab Status	OK
Sample comment	
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-APR-23
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (alexking1) 19 Jun 2015 16:07:16

Generated On: 20 Jul 2016 07:11:43

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (alexking1) 19 Jun 2015 16:07:00
Generated On: 20 Jul 2016 07:11:43

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

Date of assessment	2014 APR 23
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?	Extremely
-------------------------------	-----------

3. Did you enjoy the sensation in your throat and chest?	Extremely
--	-----------

4. Did smoking calm you down?	Extremely
-------------------------------	-----------

5. Did smoking make you feel more awake?	A lot
--	-------

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?	Not at all
---	------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (alexking1) 19 Jun 2015 16:07:00
Generated On: 20 Jul 2016 07:11:43

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? Not at all ☐

12. Did you enjoy smoking? Extremely ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Human Smoking Topography Questionnaire
Data signed: (alexking1) 19 Jun 2015 16:06:58
Generated On: 20 Jul 2016 07:11:43

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	
-----------------	--

Date of assessment	23 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:00 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.	Strongly agree <input checked="" type="radio"/>
--	---

If you agree or strongly agree, please describe :	CIGARETT SMOKE FASTER WITH THE DEVICE
---	--

2. You enjoy smoking with the device as much as without it.	Strongly disagree <input type="radio"/>
---	---

If you disagree or strongly disagree, please describe :	NO DON'T LIKE THE DEVICE DO MY CIGARETTE SMOKER FASTER
---	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Human Smoking Topography Questionnaire
Data signed: (alexking1) 19 Jun 2015 16:06:58
Generated On: 20 Jul 2016 07:11:43

3. The taste of the conventional cigarettes/products is
different with the device. _____

If you agree or strongly agree, please describe : _____

4. The device is easy to use. _____

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device. _____

If you agree or strongly agree, please describe : _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Questionnaire on smoking urges (QSU)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 APR 23
DD/MMM/YYYY	
Time of assessment	20:01
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	Do not agree or disagree <input checked="" type="radio"/>
5. All I want right now is a cigarette	Do not agree or disagree <input checked="" type="radio"/>
6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>
7. A cigarette would taste good now	Strongly agree <input checked="" type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Questionnaire on smoking urges (QSU)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Somewhat agree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	2292
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
------------------------	-------

Specimen Condition	
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Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

Lab Test Name	FIBRINOGEN
---------------	------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	274
Reported Numeric Result	274
Reference Range low	200
Reference Range high	400
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2292
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	
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Battery ID	CN236
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Battery Name	HOMOCYSTEINE
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Lab Test ID	CNT145
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Lab Test Name	HOMOCYSTEINE, EDTAPL
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	8.28
Reported Numeric Result	8.28
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2292
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	
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Battery ID	IM2293
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Battery Name	SICAM-1
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Lab Test ID	IMT1768
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Lab Test Name	SICAM-1-RUO
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	<42.2
Reported Numeric Result	
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Low ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (4)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2292
----------------------	------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	
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Battery ID	HM1054
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Battery Name	HEMOGLOBIN A1C
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Lab Test ID	HMT370
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (4)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	HEMOGLOBIN A1C,VARIANT(-70)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	5.4
Reported Numeric Result	5.4
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	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (4)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (5)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2292
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
------------------------	------------

Actual Collection Time	05:37
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Specimen Condition	
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Battery ID	RC6871
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Battery Name	HDL
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Lab Test ID	RCT1684
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (5)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	45
Reported Numeric Result	45
Reference Range low	34
Reference Range high	88
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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (5)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (6)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2292
----------------------	------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	
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Battery ID	SC3249
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Battery Name	HS-CRP
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Lab Test ID	SCT1528
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (6)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.036
Reported Numeric Result	0.036
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	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (6)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (7)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2292
----------------------	------

Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	
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Battery ID	SC3582
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Battery Name	APOLIPOPROTEIN
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Lab Test ID	SCT3639
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Lab Test Name	APOLIPOPROTEIN A1, RAND
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (7)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	117
Reported Numeric Result	117
Reference Range low	125
Reference Range high	215
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (7)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Low ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (8)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	2292
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	
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Battery ID	SC3582
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Battery Name	APOLIPOPROTEIN
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Lab Test ID	SCT3643
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Lab Test Name	APOLIPOPROTEIN B, RAND
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (8)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	68
Reported Numeric Result	68
Reference Range low	55
Reference Range high	125
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (8)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low	
SI Reference Range High	
SI Units	
Reported Result Type	
Alert Flag	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (9)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2292
----------------------	------

Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X086761
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Actual Collection Date	2014 04 23
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Actual Collection Time	05:37
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Specimen Condition	
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Battery ID	RC9267
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Battery Name	LDL
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Lab Test ID	RCT2394
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Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (9)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	93
Reported Numeric Result	93
Reference Range low	77
Reference Range high	174
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (9)
Data signed: (alexking1) 19 Jun 2015 16:07:01
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low	
SI Reference Range High	
SI Units	
Reported Result Type	
Alert Flag	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMa, HBMA)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112450005832
Analyte	HPMA
Sample type	URINE
Result	455
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112450005832
Analyte	CEMA
Sample type	URINE
Result	52.7
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	AA99128-03
Date of Collection	2014-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112450005832
Analyte	HBMA
Sample type	URINE
Result	165
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (NNN, NNAL)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112460006020
Analyte	NNAL
Sample type	URINE
Result	172
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112460006020
Analyte	NNN
Sample type	URINE
Result	3.15
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (HEMA)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (HEMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112470003578
Analyte	HEMA
Sample type	URINE
Result	7.84
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (HEMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(1)

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000784
Analyte	COT
Sample type	URINE
Result	1930
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-APR-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(1)

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000784
Analyte	COT-GLUC
Sample type	URINE
Result	1070
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-APR-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(3)

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000784
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Analyte	NIC
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Sample type	URINE
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Result	801
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-13
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Date of Collection	2014-APR-21
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Timepoint-minutes	
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Urine Start Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(4)

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000784
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Analyte	NIC-GLUC
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Sample type	URINE
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Result	220
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-13
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Date of Collection	2014-APR-21
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Timepoint-minutes	
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Urine Start Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(5)

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000784
Analyte	THCOT
Sample type	URINE
Result	3120
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-APR-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

(6)

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112550000784
Analyte	THCOT-GLUC
Sample type	URINE
Result	1800
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-APR-21
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (alexking1) 19 Jun 2015 16:07:19

Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (3-OH BaP)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112490003578
Analyte	3-OH BAP
Sample type	URINE
Result	154
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Caffeine, Paraxanthine)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample type	PLASMA
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112500000928
Analyte	CAFFEINE
Sample type	PLASMA
Result	1250
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-APR-23
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112500000928
Analyte	PARAXANTHINE
Sample type	PLASMA
Result	1650
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-APR-23
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112510003622
Analyte	1-NA
Sample type	URINE
Result	44.5
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112510003622
Analyte	2-NA
Sample type	URINE
Result	14.7
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112510003622
Analyte	4-ABP
Sample type	URINE
Result	8.03
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112510003622
Analyte	O-TOL
Sample type	URINE
Result	82.2
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (11-dTXb2)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112530002250
Analyte	11-DTXB2
Sample type	URINE
Result	633
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (iPF2a-III)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112540002082
Analyte	IPF2A-III
Sample type	URINE
Result	281
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:17
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Ames)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Ames) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05113320000484
Analyte	AMES
Sample type	URINE
Result	19.7
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Ames) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:19
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (1-OHP)
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115190004722
Analyte	1-OHP
Sample type	URINE
Result	206
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (SPMA, SBMA)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115170004933
Analyte	SBMA
Sample type	URINE
Result	5.10
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115170004933
Analyte	SPMA
Sample type	URINE
Result	2.12
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (MHBMA)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115180000707
Analyte	MHBMA
Sample type	URINE
Result	1.02
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Creatinine)
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05115160003050
Analyte	CREATININE
Sample type	URINE
Result	65.0
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-APR-23
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample type	PLASMA
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112440000711
Analyte	COT
Sample type	PLASMA
Result	374
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-APR-23
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112440000711
Analyte	NIC
Sample type	PLASMA
Result	37.9
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-APR-23
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112520000928
Analyte	COT
Sample type	PLASMA
Result	372
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-APR-23
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Sample Barcode	05112520000928
Analyte	THCOT
Sample type	PLASMA
Result	105
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-APR-23
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)
Data signed: (alexking1) 19 Jun 2015 16:07:18
Generated On: 20 Jul 2016 07:11:43

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 1

Form: Date of Visit

Data signed: (alexking1) 19 Jun 2015 16:07:20

Generated On: 20 Jul 2016 07:11:43

Date of Visit

24 APR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: Vital Signs
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Were Vitals Signs assessed?

No ☒

If No, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Has the subject smoked within 15 minutes prior to
assessment

Time of assessment

Pulse rate

Respiratory rate

Blood Pressure (systolic)

Blood Pressure (diastolic)

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: Plasma Nicotine Sample
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: Plasma Cotinine Sample
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: CoHb Blood Sample
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: CO Breath Test <SA arm/> (1)
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
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Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: CO Breath Test <SA arm/> (2)
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
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Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: CO Breath Test <SA arm/> (3)
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 1

Form: CO Breath Test <SA arm/> (4)

Data signed: (alexking1) 19 Jun 2015 16:07:21

Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: 24 hour urine collections
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Start Time

End Date

End Time

Volume

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: Sample Urine Collection
Data signed: (alexking1) 19 Jun 2015 16:07:20
Generated On: 20 Jul 2016 07:11:43

Were samples for 24h collected?

No ☒

If No, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

How many primary tubes were collected?

How many back up tubes were collected?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 24
DD/MMM/YYYY

Time of assessment

06:15
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?

Severe ☐

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 1
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

How have you been feeling over the past 24 hours? Severe ☐

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? Severe ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Severe ☐

8. Restless

How have you been feeling over the past 24 hours? Moderate ☐

9. Impatient

How have you been feeling over the past 24 hours? Moderate ☐

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, Dallas, Texas: 2292
Folder: Day 1
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Day 1
Form: Cough Assessment
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 24
DD/MMM/YYYY

Time of assessment

06:10
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, Dallas, Texas: 2292

Folder: Day 2

Form: Date of Visit

Data signed: (alexking1) 19 Jun 2015 16:07:21

Generated On: 20 Jul 2016 07:11:43

Date of Visit

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 2
Form: Vital Signs
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Were Vitals Signs assessed?

No ☒

If No, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Has the subject smoked within 15 minutes prior to
assessment

Time of assessment

Pulse rate

Respiratory rate

Blood Pressure (systolic)

Blood Pressure (diastolic)

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 2
Form: Plasma Nicotine Sample
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 2
Form: Plasma Cotinine Sample
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 2
Form: CoHb Blood Sample
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 2
Form: CO Breath Test <SA arm/> (1)
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
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Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 2
Form: CO Breath Test <SA arm/> (2)
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 2
Form: CO Breath Test <SA arm/> (3)
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 2
Form: CO Breath Test <SA arm/> (4)
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 2
Form: 24 hour urine collections
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

Start Time	
End Date	
End Time	
Volume	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 2
Form: Sample Urine Collection
Data signed: (alexking1) 19 Jun 2015 16:07:21
Generated On: 20 Jul 2016 07:11:43

Were samples for 24h collected?

No ☒

If No, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

How many primary tubes were collected?

How many back up tubes were collected?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 3

Form: Date of Visit

Data signed: (alexking1) 19 Jun 2015 16:07:22

Generated On: 20 Jul 2016 07:11:43

Date of Visit

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 3

Form: Vital Signs

Data signed: (alexking1) 19 Jun 2015 16:07:22

Generated On: 20 Jul 2016 07:11:43

Were Vitals Signs assessed?

No ☒

If No, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Has the subject smoked within 15 minutes prior to
assessment

Time of assessment

Pulse rate

Respiratory rate

Blood Pressure (systolic)

Blood Pressure (diastolic)

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (alexking1) 19 Jun 2015 16:07:22

Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 3
Form: Plasma Cotinine Sample
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 3
Form: CoHb Blood Sample
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 3
Form: CO Breath Test <SA arm/> (1)
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 3
Form: CO Breath Test <SA arm/> (2)
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 3
Form: CO Breath Test <SA arm/> (3)
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 3
Form: CO Breath Test <SA arm/> (4)
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 3
Form: 24 hour urine collections
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Start Time	
End Date	
End Time	
Volume	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 3
Form: Sample Urine Collection
Data signed: (alexking1) 19 Jun 2015 16:07:22
Generated On: 20 Jul 2016 07:11:43

Were samples for 24h collected?

No ☒

If No, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

How many primary tubes were collected?

How many back up tubes were collected?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 4

Form: Date of Visit

Data signed: (alexking1) 19 Jun 2015 16:07:23

Generated On: 20 Jul 2016 07:11:43

Date of Visit

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 4

Form: Vital Signs

Data signed: (alexking1) 19 Jun 2015 16:07:23

Generated On: 20 Jul 2016 07:11:43

Were Vitals Signs assessed?

No ☒

If No, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Has the subject smoked within 15 minutes prior to
assessment

Time of assessment

Pulse rate

Respiratory rate

Blood Pressure (systolic)

Blood Pressure (diastolic)

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 4
Form: Socio-Economic Status
Data signed: (alexking1) 19 Jun 2015 16:07:23
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used?

No ☐

Reason not done

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date

Time

Q1. What is the highest level of education you have completed?

Q2. What is your current occupational status?

SPECIFY

Q3. How many people are currently living in your household, including yourself?

Q4. Of these people, how many are children?

Q5. Of these people, how many are adults?

Q6. Of the adults, how many bring income into the household?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 4

Form: Socio-Economic Status

Data signed: (alexking1) 19 Jun 2015 16:07:23

Generated On: 20 Jul 2016 07:11:43

Q7. Which of these categories best describes your total combined family income for the past 12 months? This should include income (before taxes) from all sources, wages, rent from properties, social security, disability and/or veteran's benefits, unemployment benefits, workman's compensation, help from relatives (including child payments and alimony), and so on.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 4

Form: Plasma Nicotine Sample

Data signed: (alexking1) 19 Jun 2015 16:07:23

Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 4

Form: Plasma Cotinine Sample

Data signed: (alexking1) 19 Jun 2015 16:07:23

Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 4

Form: CoHb Blood Sample

Data signed: (alexking1) 19 Jun 2015 16:07:23

Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Date DD/MMM/YYYY	<hr/>
---------------------	-------

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
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Time hour:min 24-hour clock	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 4
Form: CO Breath Test <SA arm/> (1)
Data signed: (alexking1) 19 Jun 2015 16:07:23
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 4
Form: CO Breath Test <SA arm/> (2)
Data signed: (alexking1) 19 Jun 2015 16:07:23
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 4
Form: CO Breath Test <SA arm/> (3)
Data signed: (alexking1) 19 Jun 2015 16:07:23
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 4
Form: CO Breath Test <SA arm/> (4)
Data signed: (alexking1) 19 Jun 2015 16:07:23
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 4
Form: 24 hour urine collections
Data signed: (alexking1) 19 Jun 2015 16:07:23
Generated On: 20 Jul 2016 07:11:43

Start Time	
End Date	
End Time	
Volume	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 4
Form: Sample Urine Collection
Data signed: (alexking1) 19 Jun 2015 16:07:23
Generated On: 20 Jul 2016 07:11:43

Were samples for 24h collected?

No ☒

If No, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

How many primary tubes were collected?

How many back up tubes were collected?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Date of Visit

Data signed: (alexking1) 19 Jun 2015 16:07:26

Generated On: 20 Jul 2016 07:11:43

Date of Visit

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Vital Signs

Data signed: (alexking1) 19 Jun 2015 16:07:26

Generated On: 20 Jul 2016 07:11:43

Were Vitals Signs assessed?

No ☒

If No, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Has the subject smoked within 15 minutes prior to
assessment

Time of assessment

Pulse rate

Respiratory rate

Blood Pressure (systolic)

Blood Pressure (diastolic)

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Plasma Nicotine Sample

Data signed: (alexking1) 19 Jun 2015 16:07:26

Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Plasma Cotinine Sample

Data signed: (alexking1) 19 Jun 2015 16:07:26

Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: CoHb Blood Sample(SA) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:26
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: CoHb Blood Sample(SA) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:26
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: CoHb Blood Sample(SA) (3)

Data signed: (alexking1) 19 Jun 2015 16:07:26

Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: CoHb Blood Sample(SA) (4)
Data signed: (alexking1) 19 Jun 2015 16:07:26
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: CO Breath Test <SA arm/> (1)
Data signed: (alexking1) 19 Jun 2015 16:07:26
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: CO Breath Test <SA arm/> (2)
Data signed: (alexking1) 19 Jun 2015 16:07:26
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: CO Breath Test <SA arm/> (3)
Data signed: (alexking1) 19 Jun 2015 16:07:26
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: CO Breath Test <SA arm/> (4)

Data signed: (alexking1) 19 Jun 2015 16:07:26

Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: CYP1A2 activity Sample

Data signed: (alexking1) 19 Jun 2015 16:07:23

Generated On: 20 Jul 2016 07:11:43

Time of caffeine tablet intake

Sample collection Not Done

True

If Not Done, please specify the reason:

SUBJECT VOLUNTARILY WITHDREW CONSENT

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

Caffeine

Paraxanthine

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: 24 hour urine collections
Data signed: (alexking1) 19 Jun 2015 16:07:26
Generated On: 20 Jul 2016 07:11:43

Start Time

End Date

End Time

Volume

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Sample Urine Collection
Data signed: (alexking1) 19 Jun 2015 16:07:26
Generated On: 20 Jul 2016 07:11:43

Were samples for 24h collected?

No ☒

If No, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

How many primary tubes were collected?

How many back up tubes were collected?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Behavioral Risk Factor Surveillance System Questionnaire
Data signed: (alexking1) 19 Jun 2015 16:07:23
Generated On: 20 Jul 2016 07:11:43

Type	BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM QUESTIONNAIRE
------	--

Was paper questionnaire used?	No <input checked="" type="radio"/>
-------------------------------	-------------------------------------

Reason not done	SUBJECT VOLUNTARILY WITHDREW CONSENT
-----------------	---

Date of assessment	_____
--------------------	-------

Time of assessment	_____
--------------------	-------

Have you ever smoked 100 cigarettes or more in your life?	_____
---	-------

Do you now smoke cigarettes every day, some days, or not at all?	_____
--	-------

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?	_____
--	-------

How long has it been since you last smoked a cigarette, even one or two puffs?	_____
--	-------

Do you currently use chewing tobacco, snuff, or snus every day, some days, or 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, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	No <input type="radio"/>
-------------------------------	--------------------------

Reason not done	SUBJECT VOLUNTARILY WITHDREW CONSENT
-----------------	---

Date of assessment	<hr/>
--------------------	-------

Time of assessment	<hr/>
--------------------	-------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	<hr/>
---	-------

2. Have you ever smoked 100 cigarettes or more in your life?	<hr/>
---	-------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	<hr/>
---	-------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	<hr/>
--	-------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	<hr/>
---	-------

Years	<hr/>
-------	-------

Months	<hr/>
--------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (alexking1) 19 Jun 2015 16:07:24

Generated On: 20 Jul 2016 07:11:43

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you
predominantly smoke in the last 12 months of smoking? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	No <input type="radio"/>
-------------------------------	--------------------------

Reason not done	SUBJECT VOLUNTARILY WITHDREW CONSENT
-----------------	---

Date of assessment	<hr/>
--------------------	-------

Time of assessment	<hr/>
--------------------	-------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	<hr/>
---	-------

2. Have you ever smoked 100 cigarettes or more in your life?	<hr/>
---	-------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	<hr/>
---	-------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	<hr/>
--	-------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

Months	<hr/>
--------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (1)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you
predominantly smoke in the last 12 months of smoking?

Time _____

Currently (last 3 months) ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per
day?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (alexking1) 19 Jun 2015 16:07:24

Generated On: 20 Jul 2016 07:11:43

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	No <input type="radio"/>
-------------------------------	--------------------------

Reason not done	SUBJECT VOLUNTARILY WITHDREW CONSENT
-----------------	---

Date of assessment	<hr/>
--------------------	-------

Time of assessment	<hr/>
--------------------	-------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	<hr/>
---	-------

2. Have you ever smoked 100 cigarettes or more in your life?	<hr/>
---	-------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	<hr/>
---	-------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	<hr/>
--	-------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

Months	<hr/>
--------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (2)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you
predominantly smoke in the last 12 months of smoking? _____

Time _____

1 year ago ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day? _____

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day? _____

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per
day? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (alexking1) 19 Jun 2015 16:07:24

Generated On: 20 Jul 2016 07:11:43

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	No <input type="radio"/>
-------------------------------	--------------------------

Reason not done	SUBJECT VOLUNTARILY WITHDREW CONSENT
-----------------	---

Date of assessment	<hr/>
--------------------	-------

Time of assessment	<hr/>
--------------------	-------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	<hr/>
---	-------

2. Have you ever smoked 100 cigarettes or more in your life?	<hr/>
---	-------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	<hr/>
---	-------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	<hr/>
--	-------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

Months	<hr/>
--------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (3)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you
predominantly smoke in the last 12 months of smoking? _____

Time _____

5 years ago 

8. On average, how many Manufactured cigarettes
do/did you smoke per day? _____

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day? _____

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per
day? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (alexking1) 19 Jun 2015 16:07:24

Generated On: 20 Jul 2016 07:11:43

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (4)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	No <input type="radio"/>
-------------------------------	--------------------------

Reason not done	SUBJECT VOLUNTARILY WITHDREW CONSENT
-----------------	---

Date of assessment	<hr/>
--------------------	-------

Time of assessment	<hr/>
--------------------	-------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	<hr/>
---	-------

2. Have you ever smoked 100 cigarettes or more in your life?	<hr/>
---	-------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	<hr/>
---	-------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	<hr/>
--	-------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	<hr/>
---	-------

Years	<hr/>
-------	-------

Months	<hr/>
--------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (4)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you
predominantly smoke in the last 12 months of smoking? _____

Time _____

10 years ago ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day? _____

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day? _____

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per
day? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (alexking1) 19 Jun 2015 16:07:24

Generated On: 20 Jul 2016 07:11:43

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (5)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	No <input type="radio"/>
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Reason not done	SUBJECT VOLUNTARILY WITHDREW CONSENT
-----------------	---

Date of assessment	<hr/>
--------------------	-------

Time of assessment	<hr/>
--------------------	-------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	<hr/>
---	-------

2. Have you ever smoked 100 cigarettes or more in your life?	<hr/>
---	-------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	<hr/>
---	-------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	<hr/>
--	-------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

Months	<hr/>
--------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (5)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you
predominantly smoke in the last 12 months of smoking? _____

Time

15 years ago 

8. On average, how many Manufactured cigarettes
do/did you smoke per day? _____

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day? _____

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per
day? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (alexking1) 19 Jun 2015 16:07:24

Generated On: 20 Jul 2016 07:11:43

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (6)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	No <input type="radio"/>
-------------------------------	--------------------------

Reason not done	SUBJECT VOLUNTARILY WITHDREW CONSENT
-----------------	---

Date of assessment	<hr/>
--------------------	-------

Time of assessment	<hr/>
--------------------	-------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	<hr/>
---	-------

2. Have you ever smoked 100 cigarettes or more in your life?	<hr/>
---	-------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	<hr/>
---	-------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	<hr/>
--	-------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

Months	<hr/>
--------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (6)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you
predominantly smoke in the last 12 months of smoking? _____

Time _____

20 years ago ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day? _____

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day? _____

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per
day? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (alexking1) 19 Jun 2015 16:07:24

Generated On: 20 Jul 2016 07:11:43

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (7)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	No <input type="radio"/>
-------------------------------	--------------------------

Reason not done	SUBJECT VOLUNTARILY WITHDREW CONSENT
-----------------	---

Date of assessment	<hr/>
--------------------	-------

Time of assessment	<hr/>
--------------------	-------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	<hr/>
---	-------

2. Have you ever smoked 100 cigarettes or more in your life?	<hr/>
---	-------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	<hr/>
---	-------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	<hr/>
--	-------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
-------	-------

Months	<hr/>
--------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Smoking Questionnaire (SQ) (7)
Data signed: (alexking1) 19 Jun 2015 16:07:24
Generated On: 20 Jul 2016 07:11:43

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you
predominantly smoke in the last 12 months of smoking?

Time _____

More than 20 years ago ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per
day?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (alexking1) 19 Jun 2015 16:07:24

Generated On: 20 Jul 2016 07:11:43

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Supplemental Questions
Data signed: (alexking1) 19 Jun 2015 16:07:25
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date of Assessment

Time of assessment

1. How long it takes for the subject to complete the SQ

Comments (open-end)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Supplemental Questions (1)
Data signed: (alexking1) 19 Jun 2015 16:07:25
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date of Assessment

Time of assessment

1. How long it takes for the subject to complete the SQ

Question

2. Did the SQ capture your
smoking behavior
completely? ☒

Answer

Comments (open-end)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Supplemental Questions (2)
Data signed: (alexking1) 19 Jun 2015 16:07:25
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date of Assessment

Time of assessment

1. How long it takes for the subject to complete the SQ

Question

3. Did the SQ capture your
smoking behavior
correctly? ☒

Answer

Comments (open-end)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Supplemental Questions (3)
Data signed: (alexking1) 19 Jun 2015 16:07:25
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date of Assessment

Time of assessment

1. How long it takes for the subject to complete the SQ

Question

4. Did the SQ capture your
smoking history
completely? ☒

Answer

Comments (open-end)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Supplemental Questions (4)
Data signed: (alexking1) 19 Jun 2015 16:07:25
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date of Assessment

Time of assessment

1. How long it takes for the subject to complete the SQ

Question

5. Did the SQ capture your
smoking history correctly? ☒

Answer

Comments (open-end)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Supplemental Questions (5)
Data signed: (alexking1) 19 Jun 2015 16:07:25
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date of Assessment

Time of assessment

1. How long it takes for the subject to complete the SQ

Question

6. Was the SQ ☒
self-explaining?

Answer

Comments (open-end)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 5
Form: Supplemental Questions (6)
Data signed: (alexking1) 19 Jun 2015 16:07:25
Generated On: 20 Jul 2016 07:11:43

Was paper questionnaire used? No ☒

Reason not done SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date of Assessment _____

Time of assessment _____

1. How long it takes for the subject to complete the SQ _____

Question 7. Was the SQ easy to use? ☒

Answer _____

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 6

Form: Date of Visit

Data signed: (alexking1) 19 Jun 2015 16:07:26

Generated On: 20 Jul 2016 07:11:43

Date of Visit

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 6
Form: Plasma Nicotine Sample
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 6
Form: Plasma Cotinine Sample
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 6
Form: CoHb Blood Sample <prior to gas transfer>
Data signed: (alexking1) 19 Jun 2015 16:07:26
Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Timepoint	Prior to gas transfer assessment <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 6

Form: Oxysterols

Data signed: (alexking1) 19 Jun 2015 16:07:26

Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT VOLUNTARILY WITHDREW CONSENT
---	---

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

Date DD/MMM/YYYY	_____
---------------------	-------

Time hour:min 24-hour clock	_____
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 6

Form: CYP2A6 activity Sample

Data signed: (alexking1) 19 Jun 2015 16:07:26

Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:

SUBJECT VOLUNTARILY WITHDREW CONSENT

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
--	---	-----------

		trans-3'-hydroxyc otinine
--	--	------------------------------

		cotinine
--	--	----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 6

Form: Risk Marker: sICAM-1

Data signed: (alexking1) 19 Jun 2015 16:07:26

Generated On: 20 Jul 2016 07:11:43

Not Done	True
----------	------

If Not Done, please specify the reason:

SUBJECT VOLUNTARILY
WITHDREW CONSENT

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Day 6
Form: Bio-banking (Transcriptomics)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Was a Bio-banking sample for transcriptomics taken? _____

Time of Sample Collection _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 6

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken? _____

Time of Sample Collection _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Day 6

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Was a Bio-banking sample for nasal epithelial
collection/buccal collection taken? _____

Time of Buccal Collection _____

Time of Nasal Epithelial Collection _____

Was the subject fasting for at least 30 minutes at time of
sample collection? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Discharge (Confinement)
Form: Date of Discharge
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of Visit	24 APR 2014 DD/MMM/YYYY
---------------	----------------------------

Discharge Time	<hr/>
----------------	-------

Is the subject continuing in the ambulatory period?	No <input checked="" type="radio"/>
---	-------------------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Discharge (Confinement)
Form: Advice on the risk of smoking and debriefing
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Has the subject received advices on the risks of smoking?

No ☒

Has a debriefing been performed about THS 2.2?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Discharge (Confinement)
Form: Weight
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Measurement(s) assessed?

No ☒

If No, please specify the reason:

NOT REQUIRED

Date of Assessment

Time of assessment

Weight

BMI

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Discharge (Confinement)
Form: Gas Transfer
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Was the Gas Transfer performed?

No ☐

If No, please specify the reason:

NOT REQUIRED

Category

Position

SITTING

Date of assessment
DD/MMM/YYYY

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, Dallas, Texas: 2292
Folder: Discharge (Confinement)
Form: Lung Volume Measurements
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Were the Lung Volume Measurements performed?

No ☐

If No, please specify the reason:

NOT REQUIRED

Category

Position

SITTING

Date of assessment
DD/MMM/YYYY

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, Dallas, Texas: 2292
Folder: Discharge (Confinement)
Form: Spirometry with a short-acting bronchodilator
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Was the Spirometry with a short-acting bronchodilator performed?

No ☒

If No, please specify the reason:

NOT REQUIRED

Category

With short-acting
bronchodilator ☒

Position

SITTING

Date of assessment
DD/MMM/YYYY

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Discharge (Confinement)
Form: Spirometry with a short-acting bronchodilator
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Percent of predicted FEV1 value

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, Dallas, Texas: 2292
Folder: Discharge (Confinement)
Form: Urine analysis
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Were samples collected? _____

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Discharge (Confinement)
Form: Urine Pregnancy Test
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Not Done	True
If Not Done, specify reason	NOT REQUIRED
Date of Test	
Time of Test	
Specify result	
If unclear, please confirm with FSH test	
Specify result of FSH test	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Discharge (Confinement)
Form: CO Breath Test
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	NOT REQUIRED
---	--------------

Actual Time of Assessment	<hr/>
---------------------------	-------

Result	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (1)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 2014
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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	06:30
----------------------	-------

Time of butt return	06:40
---------------------	-------

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (2)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	08:47
----------------------	-------

Time of butt return	08:53
---------------------	-------

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (3)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	11:34
----------------------	-------

Time of butt return	11:42
---------------------	-------

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 2014
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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	13:30
----------------------	-------

Time of butt return	13:37
---------------------	-------

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (5)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	13:37
----------------------	-------

Time of butt return	13:45
---------------------	-------

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 2014
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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	16:45
----------------------	-------

Time of butt return	16:57
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (7)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	17:22
----------------------	-------

Time of butt return	17:29
---------------------	-------

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (8)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	18:49
----------------------	-------

Time of butt return	18:56
---------------------	-------

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	20:58
----------------------	-------

Time of butt return	21:07
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (10)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	21:08
----------------------	-------

Time of butt return	21:16
---------------------	-------

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	21:16
----------------------	-------

Time of butt return	21:23
---------------------	-------

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (12)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	21:46
----------------------	-------

Time of butt return	21:55
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
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Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (13)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 2014
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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	21:55
----------------------	-------

Time of butt return	22:05
---------------------	-------

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (14)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	22:05
----------------------	-------

Time of butt return	22:18
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (15)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	22 APR 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	22:30
----------------------	-------

Time of butt return	22:40
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (16)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	09:26
----------------------	-------

Time of butt return	09:41
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251003
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Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (17)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	11:47
----------------------	-------

Time of butt return	11:56
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (18)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	11:56
----------------------	-------

Time of butt return	12:07
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (19)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	13:28
----------------------	-------

Time of butt return	13:37
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (20)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	13:47
----------------------	-------

Time of butt return	13:50
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251007
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (21)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	14:37
----------------------	-------

Time of butt return	14:45
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251008
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	16:10
----------------------	-------

Time of butt return	16:20
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251009
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	16:41
----------------------	-------

Time of butt return	16:52
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251010
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	16:52
----------------------	-------

Time of butt return	16:57
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251011
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (25)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	18:37
----------------------	-------

Time of butt return	18:48
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251012
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (26)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	18:48
----------------------	-------

Time of butt return	18:55
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251013
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (27)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	19:55
----------------------	-------

Time of butt return	20:04
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251014
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	20:04
----------------------	-------

Time of butt return	20:16
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251015
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (29)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	20:38
----------------------	-------

Time of butt return	20:44
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251016
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	20:44
----------------------	-------

Time of butt return	20:49
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251017
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	21:04
----------------------	-------

Time of butt return	21:12
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251019
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (32)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	21:14
----------------------	-------

Time of butt return	21:21
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251020
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (33)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	21:22
----------------------	-------

Time of butt return	21:32
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251021
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (34)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 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	22:05
----------------------	-------

Time of butt return	22:15
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251022
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Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Product administration-mCC (35)
Data signed: (alexking1) 19 Jun 2015 16:07:27
Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	23 APR 2014
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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	22:16
----------------------	-------

Time of butt return	22:26
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	82
---------------------	----

SODIM sample holder number	251
----------------------------	-----

SODIM file number	VAL10082COHN10251023
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Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (alexking1) 19 Jun 2015 16:07:27

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (alexking1) 19 Jun 2015 16:07:34

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (alexking1) 19 Jun 2015 16:07:34

Generated On: 20 Jul 2016 07:11:43

Date of product use DD/MMM/YYYY	21 APR 2014
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Visit	Day -2 <input checked="" type="radio"/>
-------	---

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	16:29
----------------------	-------

Time of product return	16:33
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
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Tobacco plug kit number	<hr/>
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Tobacco plug vial number	<hr/>
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SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (alexking1) 19 Jun 2015 16:07:34

Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (1)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (2)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (3)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (4)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (5)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (6)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (7)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (8)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (9)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (10)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (11)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (12)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (13)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (14)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (15)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (16)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251003
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0082COHN10251003
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (17)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251004
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0082COHN10251004
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (18)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251005
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251005
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (19)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251006
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251006
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (20)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251007
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File Status	Error 
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Rejection / Error reason	INVERSED PIPE
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251007
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (21)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251008
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File Status	Error 
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Rejection / Error reason	NB. PUFFS < 3
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251008
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (22)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251009
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251009
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (23)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251010
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0082COHN10251010
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (24)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251011
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0082COHN10251011
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (25)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251012
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251012
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (26)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251013
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File Status	Error 
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Rejection / Error reason	NB. PUFFS < 3
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251013
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (27)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251014
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (28)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251015
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251015
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (29)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251016
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251016
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (30)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251017
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File Status	Error 
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Rejection / Error reason	NB. PUFFS < 3
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251017
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (31)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251019
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251018
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (32)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251020
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0082COHN10251020
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (33)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251021
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0082COHN10251021
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (34)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251022
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251022
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Product Use
Form: Topography files status for mCC (35)
Generated On: 20 Jul 2016 07:11:43

SODIM file number	VAL10082COHN10251023
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	05 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0082COHN10251023
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (alexking1) 19 Jun 2015 16:07:34

Generated On: 20 Jul 2016 07:11:43

Was there any Adverse Event for this subject?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (alexking1) 19 Jun 2015 16:07:34

Generated On: 20 Jul 2016 07:11:43

Has the subject taken previous or concomitant
medication?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Previous and Concomitant Medication
Form: Previous and Concomitant Medication (1)
Data signed: (alexking1) 19 Jun 2015 16:07:34
Generated On: 20 Jul 2016 07:11:43

Brand Name	DEPO-PROVERA
Start Date DD/MMM/YYYY	UN UNK 2013
Stop Date DD/MMM/YYYY	
Ongoing at final contact	True
Total Daily dose - Dose	
Total Daily dose - Unit	
Route	Intramuscular Route of Administration <input checked="" type="radio"/>
Indication	BIRTH CONTROL
Concomitant Disease Number	
AE Number	
Other	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Previous and Concomitant Medication
Form: Previous and Concomitant Medication (2)
Data signed: (alexking1) 19 Jun 2015 16:07:34
Generated On: 20 Jul 2016 07:11:43

Brand Name	IBUPROFEN
Start Date DD/MMM/YYYY	03 SEP 2013
Stop Date DD/MMM/YYYY	08 APR 2014
Ongoing at final contact	False
Total Daily dose - Dose	600
Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
Route	Oral Route of Administration <input checked="" type="radio"/>
Indication	TOOTHACHE
Concomitant Disease Number	2
AE Number	
Other	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder

Data signed: (alexking1) 19 Jun 2015 16:07:35

Generated On: 20 Jul 2016 07:11:43

Were there any events with the device?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Device Events
Form: Device report - THS 2.2 menthol Cigarette Holder (1)
Data signed: (alexking1) 19 Jun 2015 16:07:35
Generated On: 20 Jul 2016 07:11:43

Were there any events with the device?

No ☒

Event Log Number

Date of Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to Device Type:

THS 2.2 CIGARETTE HOLDER

Unique Device Identifier Serial Number

Event Description

Other Describe

Severity of Event

Adverse Event
Relationship

If Related to AE, AE Number

Solution Proposed:

If the device was replaced, New Device Serial Number:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Device Events
Form: Device report - THS 2.2 menthol Cigarette Holder (1)
Data signed: (alexking1) 19 Jun 2015 16:07:35
Generated On: 20 Jul 2016 07:11:43

Date of Device Event Closure
DD/MMM/YYYY

Time of Device Event Closure
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Device Events
Form: Device report - THS 2.2 menthol Charging Unit
Data signed: (alexking1) 19 Jun 2015 16:07:35
Generated On: 20 Jul 2016 07:11:43

Were there any events with the device?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Device Events
Form: Device report - THS 2.2 menthol Charging Unit (1)
Data signed: (alexking1) 19 Jun 2015 16:07:35
Generated On: 20 Jul 2016 07:11:43

Were there any events with the device?

No ☒

Event Log Number

Date of Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to
Device Type:

THS 2.2 CHARGING UNIT

Unique Device Identifier Serial Number

Event Description

Other Describe

Severity of Event

Adverse Event
Relationship

Solution Proposed:

If the device was replaced, New Device Serial Number:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Device Events
Form: Device report - THS 2.2 menthol Charging Unit (1)
Data signed: (alexking1) 19 Jun 2015 16:07:35
Generated On: 20 Jul 2016 07:11:43

Date of Device Event Closure
DD/MMM/YYYY

Time of Device Event Closure
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Device Inventory
Form: Device Inventory - THS 2.2 menthol Cigarette Holder (1)
Data signed: (alexking1) 19 Jun 2015 16:07:35
Generated On: 20 Jul 2016 07:11:43

Device Inventory	1
Log Number	

Date of Device Distribution	21 APR 2014
DD/MMM/YYYY	

Time of	16:29
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1249420
----------------------	---------

Date of Device Collection	21 APR 2014
DD/MMM/YYYY	

Time of	16:33
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Device Inventory
Form: Device Inventory - THS 2.2 menthol Charging Unit (1)
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Device Inventory	1
Log Number	

Date of Device Distribution	21 APR 2014
DD/MMM/YYYY	

Time of	16:29
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
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Device Serial Number	1318309
----------------------	---------

Date of Device Collection	21 APR 2014
DD/MMM/YYYY	

Time of	16:33
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (1)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
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Lab Test ID	RCT19
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Lab Test Name	TRIGLYCERIDES (GPO)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (1)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	89
Reported Numeric Result	89
Reference Range low	45
Reference Range high	214
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (1)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (2)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
--------------	-----------------

Lab Test ID	RCT142
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Lab Test Name	FASTING GLUCOSE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (2)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	102
Reported Numeric Result	102
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (2)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (3)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
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Lab Test ID	RCT20
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (3)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	157
Reported Numeric Result	157
Reference Range low	155
Reference Range high	265
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (3)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (4)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1
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Lab Test Name	TOTAL BILIRUBIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (4)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	0.3
Reported Numeric Result	0.3
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (4)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (5)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT12
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Lab Test Name	TOTAL PROTEIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (5)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	6.7
Reported Numeric Result	6.7
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (5)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (6)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT13
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Lab Test Name	ALBUMIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (6)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	3.6
Reported Numeric Result	3.6
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (6)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (7)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1407
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Lab Test Name	ALKALINE PHOSPHATASE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (7)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	69
Reported Numeric Result	69
Reference Range low	31
Reference Range high	106
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (7)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (8)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input type="radio"/>
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Accession ID	X475785
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1408
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Lab Test Name	LDH
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (8)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	185
Reported Numeric Result	185
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (8)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (9)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT15
-------------	-------

Lab Test Name	SERUM SODIUM
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (9)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (9)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (10)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT16
-------------	-------

Lab Test Name	SERUM POTASSIUM
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (10)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	3.9
Reported Numeric Result	3.9
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (10)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (11)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Unscheduled <input type="radio"/>
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Accession ID	X475785
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------


Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT29
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Lab Test Name	DIRECT BILIRUBIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (11)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	<0.1
Reported Numeric Result	
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (11)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (12)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Unscheduled <input checked="" type="radio"/>
------------	--

Accession ID	X475785
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT3
-------------	------

Lab Test Name	GGT
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (12)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	39
Reported Numeric Result	39
Reference Range low	4
Reference Range high	49
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (12)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (13)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT392
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Lab Test Name	CREATININE (RATE BLANKED)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (13)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	0.7
Reported Numeric Result	0.7
Reference Range low	0.4
Reference Range high	1.1
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (13)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (14)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT4
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Lab Test Name	ALT (SGPT)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (14)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	19
Reported Numeric Result	19
Reference Range low	6
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (14)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (15)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT5
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Lab Test Name	AST (SGOT)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (15)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	9
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (15)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (16)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT6
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Lab Test Name	UREA NITROGEN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (16)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	6
Reported Numeric Result	6
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (16)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (17)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (17)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.40
Reported Numeric Result	0.40
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (17)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

SI Numeric Result	<hr/>
SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (18)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT100
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (18)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (18)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (19)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT102
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (19)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	MCHC
Test ID	
Test Status	Done <input 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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (19)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (20)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT11
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (20)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.21
Reported Numeric Result	0.21
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (20)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (21)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (21)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.02
Reported Numeric Result	0.02
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (21)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (22)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT13
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (22)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	250
Reported Numeric Result	250
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (22)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (23)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (23)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	50.5
Reported Numeric Result	50.5
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (23)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (24)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (24)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	40.1
Reported Numeric Result	40.1
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (24)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (25)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT17
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (25)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.0
Reported Numeric Result	6.0
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (25)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (26)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT18
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (26)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.1
Reported Numeric Result	3.1
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (26)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (27)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT19
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (27)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (27)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

SI Numeric Result	<hr/>
SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (28)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Unscheduled ☒

Accession ID X475785

Actual Collection Date 2014 05 14

Actual Collection Time 13:23

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (28)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	40
Reported Numeric Result	40
Reference Range low	34
Reference Range high	48
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (28)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (29)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (29)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.1
Reported Numeric Result	4.1
Reference Range low	4.1
Reference Range high	5.6
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (29)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (30)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Unscheduled ☒

Accession ID X475785

Actual Collection Date 2014 05 14

Actual Collection Time 13:23

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (30)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	99
Reported Numeric Result	99
Reference Range low	79
Reference Range high	98
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (30)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (31)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (31)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13.6
Reported Numeric Result	13.6
Reference Range low	11.6
Reference Range high	16.4
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (31)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

SI Numeric Result	<hr/>
SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (32)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Unscheduled ☒

Accession ID X475785

Actual Collection Date 2014 05 14

Actual Collection Time 13:23

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT7

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (32)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.72
Reported Numeric Result	6.72
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (32)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (33)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT71
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (33)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	RBC MORPHOLOGY 1
Test ID	
Test Status	Done <input type="radio"/>
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (33)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (34)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT8
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (34)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.40
Reported Numeric Result	3.40
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (34)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

SI Numeric Result	<hr/>
SI Reference Range Low	<hr/>
SI Reference Range High	<hr/>
SI Units	<hr/>
Reported Result Type	<hr/>
Alert Flag	<hr/>
Clinically Significant?	<hr/>
Comment	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (35)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT9
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (35)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	2.69
Reported Numeric Result	2.69
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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (35)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (36)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT10
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Lab Test Name	UR NITRITE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (36)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	NEGATIVE
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Reported Numeric Result	<hr/>
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Reference Range low	<hr/>
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Reference Range high	<hr/>
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Range Units	<hr/>
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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SI Numeric Result	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (36)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (37)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT2
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Lab Test Name	UR SPECIFIC GRAVITY
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (37)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done 
Reported Text Result	1.005
Reported Numeric Result	1.005
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (37)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (38)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
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Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT3
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Lab Test Name	UR PH
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (38)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
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	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (38)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (39)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Unscheduled <input type="radio"/>
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Accession ID	X475785
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Actual Collection Date	2014 05 14
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Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT43
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Lab Test Name	UR BLOOD
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (39)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID _____

Test Status Done 

Reported Text Result +1

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 _____

SI Numeric Result _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (39)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (40)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
-------------------	----------------------------------

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Unscheduled <input type="radio"/>
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Accession ID	X475785
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
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Lab Test Name	UR PROTEIN
---------------	------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (40)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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 _____

SI Numeric Result _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (40)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (41)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
-------------------	----------------------------------

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Unscheduled <input type="radio"/>
------------	-----------------------------------

Accession ID	X475785
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT5
-------------	------

Lab Test Name	UR GLUCOSE
---------------	------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (41)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	NORMAL
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Reported Numeric Result	<hr/>
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Reference Range low	<hr/>
---------------------	-------

Reference Range high	<hr/>
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Range Units	<hr/>
-------------	-------

Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
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SI Text Result	<hr/>
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SI Numeric Result	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (41)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (42)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Unscheduled <input type="radio"/>
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Accession ID	X475785
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	13:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT7
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Lab Test Name	UR BILIRUBIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (42)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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 _____

SI Numeric Result _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit >> Laboratory Assessments
Form: Lab_BU_CCLS (42)
Data signed: (alexking1) 19 Jun 2015 16:07:38
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Clinical Chemistry

Data signed: (alexking1) 19 Jun 2015 16:07:38

Generated On: 20 Jul 2016 07:11:43

Date of Sample Collection
DD/MMM/YYYY

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

14 MAY 2014

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Haematology

Data signed: (alexking1) 19 Jun 2015 16:07:38

Generated On: 20 Jul 2016 07:11:43

Date of Sample Collection
DD/MMM/YYYY

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

14 MAY 2014

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Unscheduled Visit

Form: Vital Signs

Data signed: (alexking1) 19 Jun 2015 16:07:36

Generated On: 20 Jul 2016 07:11:43

Date of assessment DD/MMM/YYYY	Time of assessment hour:min 24-hour clock	Has the subject smoked within 15 minutes prior to assessm ent	Pulse rate beats per minute	Respiratory rate breaths per minute	Blood Pressure (systolic) mmHg	Blood Pressure (diastolic) mmHg	Vital Signs Position of Subject
14 MAY 2014	12:58	No	78	14	122	76	Supine

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292

Folder: Unscheduled Visit

Form: ECG (12-Lead Standard) (1)

Data signed: (alexking1) 19 Jun 2015 16:07:38

Generated On: 20 Jul 2016 07:11:43

Date of assessment DD/MMM/YYYY	14 MAY 2014
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Position	Supine <input checked="" type="radio"/>
----------	---

Heart Rate (beats per minute)	75
----------------------------------	----

QRS Interval (msec)	86
------------------------	----

QT Interval (msec)	349
-----------------------	-----

QTcB Interval (msec)	391
-------------------------	-----

QTcF Interval	376 msec
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PR Interval (msec)	135
-----------------------	-----

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

If Abnormal, Clinical Significance	<hr/>
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If Not Clinically significant or clinically Significant, Please specify the finding(s)	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment

14 MAY 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	General Appearance <input checked="" type="radio"/>
--------	---

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

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

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

Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	HEENT <input checked="" type="radio"/> (head, eyes, ears, nose, throat)
--------	--

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

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

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

Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	Thyroid Gland <input checked="" type="radio"/>
--------	--

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

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

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

Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	Heart <input checked="" type="radio"/>
--------	--

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

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

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

Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	Chest <input checked="" type="radio"/>
--------	--

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

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

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

Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	Lungs <input checked="" type="radio"/>
--------	--

Outcome	Normal <input checked="" type="radio"/>
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Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

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

Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
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System	Gastrointestinal <input checked="" type="radio"/>
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Outcome	Normal <input checked="" type="radio"/>
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Abnormal, please specify:	<hr/>
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Clinically significant	<hr/>
------------------------	-------

Not Done	False
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Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
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System	Cardiovascular System <input checked="" type="radio"/>
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Outcome	Normal <input checked="" type="radio"/>
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Abnormal, please specify:	<hr/>
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Clinically significant	<hr/>
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Not Done	False
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Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
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System	Neurologic <input checked="" type="radio"/>
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Outcome	Normal <input checked="" type="radio"/>
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Abnormal, please specify:	<hr/>
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Clinically significant	<hr/>
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Not Done	False
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Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
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System	Skin <input checked="" type="radio"/>
--------	---------------------------------------

Outcome	Normal <input checked="" type="radio"/>
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Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

Not Done	False
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Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
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System	Back <input checked="" type="radio"/>
--------	---------------------------------------

Outcome	Normal <input checked="" type="radio"/>
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Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

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

Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
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System	Musculoskeletal <input checked="" type="radio"/>
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Outcome	Normal <input checked="" type="radio"/>
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Abnormal, please specify:	<hr/>
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Clinically significant	<hr/>
------------------------	-------

Not Done	False
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Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
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System	Abdomen <input checked="" type="radio"/>
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Outcome	Normal <input checked="" type="radio"/>
---------	---

Abnormal, please specify:	<hr/>
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Clinically significant	<hr/>
------------------------	-------

Not Done	False
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Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	Dentition <input checked="" type="radio"/>
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Outcome	Normal <input checked="" type="radio"/>
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Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

Not Done	False
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Not Done; please specify the reason:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
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System	Other <input checked="" type="radio"/>
--------	--

Outcome	<hr/>
---------	-------

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

Not Done	True
----------	------

Not Done; please specify the reason:	NOT REQUIRED
--------------------------------------	--------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	Other <input checked="" type="radio"/>
--------	--

Outcome	<hr/>
---------	-------

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

Not Done	True
----------	------

Not Done; please specify the reason:	NOT REQUIRED
--------------------------------------	--------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	Other <input checked="" type="radio"/>
--------	--

Outcome	<hr/>
---------	-------

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

Not Done	True
----------	------

Not Done; please specify the reason:	NOT REQUIRED
--------------------------------------	--------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	Other <input checked="" type="radio"/>
--------	--

Outcome	<hr/>
---------	-------

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

Not Done	True
----------	------

Not Done; please specify the reason:	NOT REQUIRED
--------------------------------------	--------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Folder: Unscheduled Visit
Form: Physical Examination 14 May 2014
Data signed: (alexking1) 19 Jun 2015 16:07:36
Generated On: 20 Jul 2016 07:11:43

Date of assessment	14 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

System	Other <input checked="" type="radio"/>
--------	--

Outcome	<hr/>
---------	-------

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	<hr/>
------------------------	-------

Not Done	True
----------	------

Not Done; please specify the reason:	NOT REQUIRED
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Form: End of study
Data signed: (alexking1) 19 Jun 2015 16:06:39
Generated On: 20 Jul 2016 07:11:43

End of study date	29 MAY 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:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2292
Form: Consent Withdrawal
Data signed: (alexking1) 19 Jun 2015 16:06:39
Generated On: 20 Jul 2016 07:11:43

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, Dallas, Texas: 2292
Form: Withdrawal
Data signed: (alexking1) 19 Jun 2015 16:06:39
Generated On: 20 Jul 2016 07:11:43

Date of withdrawal	01 MAY 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 VOLUNTARILY WITHDREW CONSENT
--------------------------------------	---

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"/>
--	--------------------------------------
