

Subject Case Report Forms

2205 (Prod: Covance Clinical Development Services, Dallas, Texas)

Generated On: 20 Jul 2016 05:29:51

All time stamps listed in this document are displayed in GMT

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Form: Subject
Data signed: (jeanellek1) 18 Jun 2015 16:46:21
Generated On: 20 Jul 2016 05:29:51

Screening number	2205
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Site number	DAL
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Subject Status

Form: Subject Status

Data signed: (jeanellek1) 18 Jun 2015 16:46:21

Generated On: 20 Jul 2016 05:29:51

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

16 MAR 2014
DD/MMM/YYYY

Randomization Date

Randomization Time

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Screening

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 16:46:26

Generated On: 20 Jul 2016 05:29:51

Date of Visit

21 FEB 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Additional Informed Consent
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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

Yes ☒

Consent Date

21 FEB 2014
DD/MMM/YYYY

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

Yes ☒

Consent Date

21 FEB 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Inclusion Criteria
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Inclusion Criteria (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Inclusion Criteria (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Inclusion Criteria (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Inclusion Criteria (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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).	<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: 2205
Folder: Screening
Form: Inclusion Criteria (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Inclusion Criteria (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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).	<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: 2205
Folder: Screening
Form: Exclusion Criteria
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Exclusion Criteria (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

Exclusion Criterion Number	1
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Exclusion Criterion	As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason).
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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: 2205
Folder: Screening
Form: Exclusion Criteria (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

Exclusion Criterion Number	7
Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥35 kg/m2. <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: 2205
Folder: Screening
Form: Exclusion Criteria (8)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (9)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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 <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: 2205
Folder: Screening
Form: Exclusion Criteria (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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
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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: 2205
Folder: Screening
Form: Exclusion Criteria (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (15)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (16)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (17)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Exclusion Criteria (18)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

Exclusion Criterion Number	19
Exclusion Criterion	The subject is an employee of the investigational site or any other parties involved in the study or of their first degree relatives (parent, sibling, and child).
Result	No
*If any has been answered Yes, subject must not be included in the study.	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Exclusion Criteria (19)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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.
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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: 2205
Folder: Screening
Form: Exclusion Criteria (20)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

Exclusion Criterion Number	21
Exclusion Criterion	For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.
Result	NA
*If any has been answered Yes, subject must not be included in the study.	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Exclusion Criteria (21)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

Exclusion Criterion Number	22
Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception <input type="radio"/>
Result	NA <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: 2205
Folder: Screening
Form: Demographics
Data signed: (jeanellek1) 18 Jun 2015 16:46:21
Generated On: 20 Jul 2016 05:29:51

Date of Birth	(b) (6)
Sex	Male <input checked="" type="radio"/>
Race	White <input checked="" type="radio"/>
Other, specify	
Ethnicity	Not Hispanic <input checked="" type="radio"/>
Date the Subject signed the Informed Consent	21 FEB 2014 DD/MMM/YYYY
Time the Subject signed the Informed Consent	09:55 hour:min 24-hour clock
Age(Derived)	40

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Medical History/Concomitant Disease
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Date of collection

21 FEB 2014
DD/MMM/YYYY

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

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Medical History/Concomitant Disease (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Date of collection	21 FEB 2014 DD/MMM/YYYY
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Has the subject experienced any past and/ or concomitant diseases?	No <input checked="" type="radio"/>
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Number	<hr/>
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Diagnosis Description	<hr/>
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Onset Date DD/MMM/YYYY	<hr/>
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Stop Date DD/MMM/YYYY	<hr/>
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Ongoing?	False
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Vital Signs<Screening/<
Data signed: (jeanellek1) 18 Jun 2015 16:46:26
Generated On: 20 Jul 2016 05:29:51

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 21 FEB 2014
DD/MMM/YYYY

Time of assessment 10:39
hour:min 24-hour clock

Pulse rate 73
beats per minute

Respiratory rate 18
breaths per minute

Blood Pressure (systolic) 121
mmHg

Blood Pressure (diastolic) 74
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 FEB 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

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

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (8)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (9)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Back ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 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: 2205
Folder: Screening
Form: Physical Examination (15)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (16)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (17)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (18)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Physical Examination (19)
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT APPLICABLE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Advice on the risk of smoking and debriefing
Data signed: (jeanellek1) 18 Jun 2015 16:46:26
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Identification of Current Cigarette Brand
Data signed: (jeanellek1) 18 Jun 2015 16:46:26
Generated On: 20 Jul 2016 05:29:51

Date	21 FEB 2014 DD/MMM/YYYY
------	----------------------------

Brand name	MARLBORO 100'S MENTHOL
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: THS 2.2 menthol product demonstration
Data signed: (jeanellek1) 18 Jun 2015 16:46:26
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Smoking History
Data signed: (jeanellek1) 18 Jun 2015 16:46:26
Generated On: 20 Jul 2016 05:29:51

Date of Assessment

21 FEB 2014
DD/MMM/YYYY

1. Does the subject plan to quit smoking during the next 6 months? No ☐

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

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

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

5. The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or nicotine-replacement therapy [NRT]), electronic cigarettes and similar devices, within 4 weeks prior to assessment. No ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Weight and Height
Data signed: (jeanellek1) 18 Jun 2015 16:46:26
Generated On: 20 Jul 2016 05:29:51

Measurement(s) assessed? Yes ☒

If No, please specify the reason: _____

Date of assessment 21 FEB 2014
DD/MMM/YYYY

Weight 112.8
kg

Height 183.5
cm

BMI (Derived) 33.5
kg/m2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 21 FEB 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 76
beats per minute

QRS Interval 85
msec

QT Interval 363
msec

QTcB Interval 408
msec

QTcF Interval 393
msec

PR Interval 144
msec

Interpretation Normal ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 16:46:22
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Spirometry (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:25
Generated On: 20 Jul 2016 05:29:51

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? Yes ☒

Date of assessment DD/MMM/YYYY 21 FEB 2014

Time of assessment 12:45

Predicted FVC value 5.69 L

Best measured FVC value 4.91 L

Percent of predicted FVC value 86 %

Best measured FEV1 value 3.74 L

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Spirometry (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:25
Generated On: 20 Jul 2016 05:29:51

Predicted FEV1 value	4.50 L
Percent of predicted FEV1 value	83 %
Calculated ratio between FEV1/FVC	0.76
MEF 25/75 value	3.14 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: 2205
Folder: Screening
Form: Spirometry (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:25
Generated On: 20 Jul 2016 05:29:51

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? Yes ☒

Date of assessment DD/MMM/YYYY 21 FEB 2014

Time of assessment 13:24

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 5.69 L

Best measured FVC value 4.72 L

Percent of predicted FVC value 82 %

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Spirometry (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:25
Generated On: 20 Jul 2016 05:29:51

Best measured FEV1 value	3.61 L
Predicted FEV1 value	4.50 L
Percent of predicted FEV1 value	80 %
Calculated ratio between FEV1/FVC	0.76
MEF 25/75 value	3.05 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: 2205

Folder: Screening

Form: Chest X-Ray

Data signed: (jeanellek1) 18 Jun 2015 16:46:26

Generated On: 20 Jul 2016 05:29:51

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

24 FEB 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Haematology
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Clinical Chemistry
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Urine analysis
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Screening
Form: Serology for HIV and Hepatitis B and C
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Screening

Form: Urine Drug Screen

Data signed: (jeanellek1) 18 Jun 2015 16:46:23

Generated On: 20 Jul 2016 05:29:51

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

Date of sample collection	21 FEB 2014 DD/MMM/YYYY
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Time of sample collection	10:19 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (jeanellek1) 18 Jun 2015 16:46:23

Generated On: 20 Jul 2016 05:29:51

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Alcohol Test
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 21 FEB 2014
DD/MMM/YYYY

Time of assessment 10:10
hour:min 24-hour clock

Result Negative ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Urine Cotinine Test
Data signed: (jeanellek1) 18 Jun 2015 16:46:23
Generated On: 20 Jul 2016 05:29:51

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

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

If Not Done, please specify the reason:	<hr/>
---	-------

Date of Sample Collection	21 FEB 2014 DD/MMM/YYYY
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Time of Sample Collection	10:19 hour:min 24-hour clock
---------------------------	---------------------------------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp CHEMISTRY(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
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Date of Sample Collection YYYY/MM/DD	21 FEB 2014
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Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp CHEMISTRY(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	GLUCOSE, SERUM
Code	001032
Result	90
Unit	MG/DL
Lower limit	65
Upper limit	99
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp CHEMISTRY(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	BUN
Code	001040
Result	15
Unit	MG/DL
Lower limit	6
Upper limit	24
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	CHOLESTEROL, TOTAL
Code	001065
Result	195
Unit	MG/DL
Lower limit	100
Upper limit	199
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input type="radio"/>
Time of Sample Collection	11:06
Analyte Name	PROTEIN, TOTAL, SERUM
Code	001073
Result	8.6
Unit	G/DL
Lower limit	6.0
Upper limit	8.5
Flag	High <input type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	ALBUMIN, SERUM
Code	001081
Result	4.5
Unit	G/DL
Lower limit	3.5
Upper limit	5.5
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	BILIRUBIN, TOTAL
Code	001099
Result	0.6
Unit	MG/DL
Lower limit	0.0
Upper limit	1.2
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	ALKALINE PHOSPHATASE, S
Code	001107
Result	63
Unit	IU/L
Lower limit	39
Upper limit	117
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	LDH
Code	001115
Result	160
Unit	IU/L
Lower limit	0
Upper limit	225
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	AST (SGOT)
Code	001123
Result	23
Unit	IU/L
Lower limit	0
Upper limit	40
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	TRIGLYCERIDES
Code	001172
Result	154
Unit	MG/DL
Lower limit	0
Upper limit	149
Flag	High <input checked="" type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	POTASSIUM, SERUM
Code	001180
Result	4.4
Unit	MMOL/L
Lower limit	3.5
Upper limit	5.2
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	SODIUM, SERUM
Code	001198
Result	139
Unit	MMOL/L
Lower limit	134
Upper limit	144
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	CREATININE, SERUM
Code	001370
Result	0.83
Unit	MG/DL
Lower limit	0.76
Upper limit	1.27
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	ALT (SGPT)
Code	001545
Result	23
Unit	IU/L
Lower limit	0
Upper limit	44
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	GGT
Code	001958
Result	32
Unit	IU/L
Lower limit	0
Upper limit	65
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	HEP C VIRUS AB
Code	140683
Result	0.2
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (jeanellek1) 18 Jun 2015 16:46:27
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp SEROLOGY(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	SEROLOGY
-----------------	----------

Date of Sample Collection YYYY/MM/DD	21 FEB 2014
---	-------------

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp SEROLOGY(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	SEROLOGY
-----------------	----------

Date of Sample Collection YYYY/MM/DD	21 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	11:06
---------------------------	-------

Analyte Name	HIV 1/O/2 ABS, QUAL
--------------	---------------------

Code	001725
------	--------

Result	NON REACTIVE
--------	--------------

Unit	
------	--

Lower limit	NON REACTIVE
-------------	--------------

Upper limit	
-------------	--

Flag	
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Clinically Significant?	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp SEROLOGY(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	SEROLOGY
-----------------	----------

Date of Sample Collection YYYY/MM/DD	21 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	11:06
---------------------------	-------

Analyte Name	HBSAG SCREEN
--------------	--------------

Code	006510
------	--------

Result	NEGATIVE
--------	----------

Unit	
------	--

Lower limit	NEGATIVE
-------------	----------

Upper limit	
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Flag	
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Clinically Significant?	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	SEROLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp HEMATOLOGY(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
-----------------	------------

Date of Sample Collection YYYY/MM/DD	21 FEB 2014
---	-------------

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp HEMATOLOGY(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	WBC
Code	005025
Result	8.5
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp HEMATOLOGY(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	RBC
Code	005033
Result	5.31
Unit	X10E6/UL
Lower limit	4.14
Upper limit	5.80
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	HEMOGLOBIN
Code	005041
Result	16.7
Unit	G/DL
Lower limit	12.6
Upper limit	17.7
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	HEMATOCRIT
Code	005058
Result	48.4
Unit	%
Lower limit	37.5
Upper limit	51.0
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input type="radio"/>
Time of Sample Collection	11:06
Analyte Name	MCV
Code	015065
Result	91
Unit	FL
Lower limit	79
Upper limit	97
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	MCH
Code	015073
Result	31.5
Unit	PG
Lower limit	26.6
Upper limit	33.0
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	MCHC
Code	015081
Result	34.5
Unit	G/DL
Lower limit	31.5
Upper limit	35.7
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	NEUTROPHILS
Code	015107
Result	64
Unit	%
Lower limit	40
Upper limit	74
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	LYMPHS
Code	015123
Result	29
Unit	%
Lower limit	14
Upper limit	46
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	EOS
Code	015149
Result	1
Unit	%
Lower limit	0
Upper limit	5
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	PLATELETS
Code	015172
Result	197
Unit	X10E3/UL
Lower limit	155
Upper limit	379
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	NEUTROPHILS (ABSOLUTE)
Code	015909
Result	5.5
Unit	X10E3/UL
Lower limit	1.4
Upper limit	7.0
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	LYMPHS (ABSOLUTE)
Code	015917
Result	2.5
Unit	X10E3/UL
Lower limit	0.7
Upper limit	3.1
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

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Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
Analyte Name	EOS (ABSOLUTE)
Code	015933
Result	0.0
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.4
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (18)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (18)
Data signed: (jeanellek1) 18 Jun 2015 16:46:28
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp URINALYSIS(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

21 FEB 2014

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp URINALYSIS(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:19
Analyte Name	SPECIFIC GRAVITY
Code	013060
Result	1.019
Unit	
Lower limit	1.005
Upper limit	1.030
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp URINALYSIS(21 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:19
Analyte Name	PH
Code	013078
Result	6.0
Unit	
Lower limit	5.0
Upper limit	7.5
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:19
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:19
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:19
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:19
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	21 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:19
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: 2205
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:29
Generated On: 20 Jul 2016 05:29:51

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 05296700010

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Screening
Form: FTND Questionnaire
Generated On: 20 Jul 2016 05:29:51

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

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

Date of assessment	2014 FEB 21
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	12:16
	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?	No <input checked="" type="radio"/>
--	-------------------------------------

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

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

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?	No <input checked="" type="radio"/>
---	-------------------------------------

6. Do you smoke even if you are so ill that you are in bed most of the day?	No <input checked="" type="radio"/>
---	-------------------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Screening

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

Data signed: (jeanellek1) 18 Jun 2015 16:46:26

Generated On: 20 Jul 2016 05:29:51

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 21 FEB 2014
DD/MMM/YYYY

Time of assessment 10:09
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: 2205
Folder: Admission (Day -2)
Form: Date of Visit
Data signed: (jeanellek1) 18 Jun 2015 16:46:35
Generated On: 20 Jul 2016 05:29:51

Date of Visit

14 MAR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: Inclusion Criteria
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: Inclusion Criteria (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Inclusion Criteria (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Inclusion Criteria (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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: 2205

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (jeanellek1) 18 Jun 2015 16:46:30

Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Exclusion Criteria
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: Exclusion Criteria (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Exclusion Criteria (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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: 2205

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (jeanellek1) 18 Jun 2015 16:46:30

Generated On: 20 Jul 2016 05:29:51

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

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m ² . <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: 2205
Folder: Admission (Day -2)
Form: Exclusion Criteria (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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: 2205

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (jeanellek1) 18 Jun 2015 16:46:30

Generated On: 20 Jul 2016 05:29:51

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: 2205

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (jeanellek1) 18 Jun 2015 16:46:30

Generated On: 20 Jul 2016 05:29:51

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (jeanellek1) 18 Jun 2015 16:46:30

Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Exclusion Criteria (8)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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: 2205

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (jeanellek1) 18 Jun 2015 16:46:30

Generated On: 20 Jul 2016 05:29:51

Exclusion Criterion Number	13
Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid. <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: 2205
Folder: Admission (Day -2)
Form: Exclusion Criteria (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Exclusion Criteria (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Exclusion Criteria (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Exclusion Criteria (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

Exclusion Criterion Number	21
Exclusion Criterion	For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.
Result	NA
*If any has been answered Yes, subject must not be included in the study.	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: Exclusion Criteria (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: Vital Signs
Data signed: (jeanellek1) 18 Jun 2015 16:46:36
Generated On: 20 Jul 2016 05:29:51

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 14:31
hour:min 24-hour clock

Pulse rate 63
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 122
mmHg

Blood Pressure (diastolic) 77
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Admission (Day -2)

Form: Product preference

Data signed: (jeanellek1) 18 Jun 2015 16:46:35

Generated On: 20 Jul 2016 05:29:51

Which Product Arm would you prefer to be randomized
to:

No preference ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: Advice on the risk of smoking and debriefing
Data signed: (jeanellek1) 18 Jun 2015 16:46:35
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: Physical Examination (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (8)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (9)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (15)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (16)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (17)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (18)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Physical Examination (19)
Data signed: (jeanellek1) 18 Jun 2015 16:46:31
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Identification of Current Cigarette Brand
Data signed: (jeanellek1) 18 Jun 2015 16:46:35
Generated On: 20 Jul 2016 05:29:51

Brand name

MARLBORO 100'S MENTHOL

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: THS 2.2 menthol product test
Data signed: (jeanellek1) 18 Jun 2015 16:46:35
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Admission (Day -2)
Form: Smoking History
Data signed: (jeanellek1) 18 Jun 2015 16:46:35
Generated On: 20 Jul 2016 05:29:51

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

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

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

5. The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or nicotine-replacement therapy [NRT]), electronic cigarettes and similar devices, within 4 weeks prior to assessment. No ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: Weight
Data signed: (jeanellek1) 18 Jun 2015 16:46:36
Generated On: 20 Jul 2016 05:29:51

Measurement(s) assessed? Yes ☒

If No, please specify the reason: _____

Time of assessment 14:48
hour:min 24-hour clock

Weight 114
kg

Waist circumference 127
cm

BMI 33.9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (jeanellek1) 18 Jun 2015 16:46:30

Generated On: 20 Jul 2016 05:29:51

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

If Not Done, please specify the reason: _____

Time of sample collection	14:23 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: 2205

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (jeanellek1) 18 Jun 2015 16:46:30

Generated On: 20 Jul 2016 05:29:51

Drug type	Result
Opiates	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: Alcohol Test
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 14:39
hour:min 24-hour clock

Result Negative ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: CO Breath Test
Data signed: (jeanellek1) 18 Jun 2015 16:46:30
Generated On: 20 Jul 2016 05:29:51

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	15:37
	hour:min 24-hour clock

Result	14
	ppm

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Admission (Day -2)
Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking
Data signed: (jeanellek1) 18 Jun 2015 16:46:35
Generated On: 20 Jul 2016 05:29:51

Was paper questionnaire used? No ☐

Reason not done QUESTIONNAIRE NOT FOUND
EVEN THOUGH DOCUMENTED
IT WAS COMPLETED; ENOTE
1172174 WAS GENERATED

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment _____

Time of assessment _____

1. Are you currently a smoker? _____

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

3. Are you seriously thinking of quitting smoking? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 16:46:42

Generated On: 20 Jul 2016 05:29:51

Date of Visit

15 MAR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Vital Signs
Data signed: (jeanellek1) 18 Jun 2015 16:46:42
Generated On: 20 Jul 2016 05:29:51

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment Yes ☒

Time of assessment 09:49
hour:min 24-hour clock

Pulse rate 98
beats per minute

Respiratory rate 18
breaths per minute

Blood Pressure (systolic) 116
mmHg

Blood Pressure (diastolic) 71
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: CoHb Blood Sample
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	15 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:01
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (jeanellek1) 18 Jun 2015 16:46:36

Generated On: 20 Jul 2016 05:29:51

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	06:33
---	-------

Result(ppm)	11
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (jeanellek1) 18 Jun 2015 16:46:36

Generated On: 20 Jul 2016 05:29:51

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	12:38
---	-------

Result(ppm)	15
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (jeanellek1) 18 Jun 2015 16:46:36

Generated On: 20 Jul 2016 05:29:51

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	16:05
---	-------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (jeanellek1) 18 Jun 2015 16:46:36

Generated On: 20 Jul 2016 05:29:51

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	20:13
---	-------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: 4 hour urine collection
Data signed: (jeanellek1) 18 Jun 2015 16:46:42
Generated On: 20 Jul 2016 05:29:51

Start Time	09:41
	hour:min 24-hour clock

End Time	13:45
	hour:min 24-hour clock

Volume	287
	mL

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Sample Urine Collection (4 Hour collection)
Data signed: (jeanellek1) 18 Jun 2015 16:46:41
Generated On: 20 Jul 2016 05:29:51

Were samples for 4h collected? Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected? 13

How many back up tubes were collected? 13

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 16:46:42
Generated On: 20 Jul 2016 05:29:51

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 15 DD/MMM/YYYY
Time of assessment	20:16 hour:min 24-hour clock
Assessment Status	Completed <input type="radio"/>
1. Was smoking satisfying?	A lot <input type="radio"/>
2. Did cigarettes taste good?	Not at all <input type="radio"/>
3. Did you enjoy the sensation in your throat and chest?	Moderately <input type="radio"/>
4. Did smoking calm you down?	Extremely <input type="radio"/>
5. Did smoking make you feel more awake?	A lot <input type="radio"/>
6. Did smoking make you feel less irritable?	A lot <input type="radio"/>
7. Did smoking help you concentrate?	A lot <input type="radio"/>
8. Did smoking reduce your hunger for food?	Little <input type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 16:46:42
Generated On: 20 Jul 2016 05:29:51

9. Did smoking make you dizzy? Little ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a cigarette? Quite a lot ☐

12. Did you enjoy smoking? Moderately ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Behavioral Risk Factor Surveillance System Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

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

Reason not done	
-----------------	--

Date of assessment	15 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:08 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: 2205
Folder: Baseline (Day -1)
Form: Behavioral Risk Factor Surveillance System Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

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

Reason not done	
-----------------	--

Date of assessment	15 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:08 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

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

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

Years	
-------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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 01 Years

Months 00 Months

Days 00 Days

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

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

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

Date of assessment	15 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:08 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	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: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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 _____ 01 Years

Months _____ 00 Months

Days _____ 00 Days

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

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? _____ None ☒

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

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

Reason not done	
-----------------	--

Date of assessment	15 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:08 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

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

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

Years	
-------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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 _____ 01 Years

Months _____ 00 Months

Days _____ 00 Days

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

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? _____ None ☒

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

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

Reason not done	
-----------------	--

Date of assessment	15 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:08 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

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

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

Years	
-------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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 01 Years

Months 00 Months

Days 00 Days

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

Time 5 years 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? None ☒

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

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

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

Date of assessment	15 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:08 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?	Yes <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: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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 _____ 01 Years

Months _____ 00 Months

Days _____ 00 Days

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

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? None ☒

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

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

Reason not done	
-----------------	--

Date of assessment	15 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:08 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

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

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

Years	
-------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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 _____ 01 Years

Months _____ 00 Months

Days _____ 00 Days

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

Time _____ 15 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☒

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☒

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

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

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

Date of assessment	15 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:08 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	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: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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 _____ 01 Years

Months _____ 00 Months

Days _____ 00 Days

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

Time _____ 20 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☒

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☒

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
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Reason not done	<hr/>
-----------------	-------

Date of assessment	15 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:08 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	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: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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 _____ 01 Years

Months _____ 00 Months

Days _____ 00 Days

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

Time _____ More than 20 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day? _____ None ☒

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? _____ None ☒

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:37
Generated On: 20 Jul 2016 05:29:51

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Supplemental Questions
Data signed: (jeanellek1) 18 Jun 2015 16:46:41
Generated On: 20 Jul 2016 05:29:51

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 15 MAR 2014
DD/MMM/YYYY

Time of assessment 20:08

1. How long it takes for the subject to complete the SQ 5 minutes

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Supplemental Questions (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:41
Generated On: 20 Jul 2016 05:29:51

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 15 MAR 2014
DD/MMM/YYYY

Time of assessment 20:08

1. How long it takes for the subject to complete the SQ 5 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: 2205
Folder: Baseline (Day -1)
Form: Supplemental Questions (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:41
Generated On: 20 Jul 2016 05:29:51

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 15 MAR 2014
DD/MMM/YYYY

Time of assessment 20:08

1. How long it takes for the subject to complete the SQ 5 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: 2205
Folder: Baseline (Day -1)
Form: Supplemental Questions (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:41
Generated On: 20 Jul 2016 05:29:51

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 15 MAR 2014
DD/MMM/YYYY

Time of assessment 20:08

1. How long it takes for the subject to complete the SQ 5 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: 2205
Folder: Baseline (Day -1)
Form: Supplemental Questions (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:41
Generated On: 20 Jul 2016 05:29:51

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 15 MAR 2014
DD/MMM/YYYY

Time of assessment 20:08

1. How long it takes for the subject to complete the SQ 5 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: 2205
Folder: Baseline (Day -1)
Form: Supplemental Questions (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:41
Generated On: 20 Jul 2016 05:29:51

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 15 MAR 2014
DD/MMM/YYYY

Time of assessment 20:08

1. How long it takes for the subject to complete the SQ 5 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Supplemental Questions (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:41
Generated On: 20 Jul 2016 05:29:51

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 15 MAR 2014
DD/MMM/YYYY

Time of assessment 20:08

1. How long it takes for the subject to complete the SQ 5 minutes

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Questionnaire on smoking urges (QSU)
Data signed: (jeanellek1) 18 Jun 2015 16:46:42
Generated On: 20 Jul 2016 05:29:51

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 MAR 15
DD/MMM/YYYY	
Time of assessment	20:15
hour:min 24-hour clock	
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Agree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <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	Somewhat agree <input type="radio"/>
5. All I want right now is a cigarette	Disagree <input type="radio"/>
6. I have an urge for a cigarette	Do not agree or disagree <input type="radio"/>
7. A cigarette would taste good now	Do not agree or disagree <input type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112450004966
Analyte	HPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112450004966
Analyte	CEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112450004966
Analyte	HBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112460006519
Analyte	NNAL
Sample type	URINE
Result	228
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112460006519
Analyte	NNN
Sample type	URINE
Result	4.28
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (HEMA)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (HEMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112470002553
Analyte	HEMA
Sample type	URINE
Result	1.60
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-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (HEMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
Data signed: (jeanellek1) 18 Jun 2015 16:46:45
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

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

(1)

Data signed: (jeanellek1) 18 Jun 2015 16:46:45

Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112550000861
Analyte	COT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

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

(1)

Data signed: (jeanellek1) 18 Jun 2015 16:46:45

Generated On: 20 Jul 2016 05:29:51

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

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

(2)

Data signed: (jeanellek1) 18 Jun 2015 16:46:45

Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112550000861
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Analyte	COT-GLUC
---------	----------

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

Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYZED IN ERROR
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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-MAR-15
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

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

(2)

Data signed: (jeanellek1) 18 Jun 2015 16:46:45

Generated On: 20 Jul 2016 05:29:51

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 16:46:45

Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112550000861
Analyte	NIC
Sample type	URINE
Result	874
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 16:46:45

Generated On: 20 Jul 2016 05:29:51

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

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

(4)

Data signed: (jeanellek1) 18 Jun 2015 16:46:45

Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112550000861
Analyte	NIC-GLUC
Sample type	URINE
Result	710
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

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

(4)

Data signed: (jeanellek1) 18 Jun 2015 16:46:45

Generated On: 20 Jul 2016 05:29:51

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:45
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112550000861
Analyte	THCOT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

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

Data signed: (jeanellek1) 18 Jun 2015 16:46:45

Generated On: 20 Jul 2016 05:29:51

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:45
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112550000861
Analyte	THCOT-GLUC
Sample type	URINE
Result	3460
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (jeanellek1) 18 Jun 2015 16:46:45

Generated On: 20 Jul 2016 05:29:51

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (3-OH BaP)
Data signed: (jeanellek1) 18 Jun 2015 16:46:45
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:45
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112490003589
Analyte	3-OH BAP
Sample type	URINE
Result	.
Result Unit	FG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-07
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:45
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112510002731
Analyte	1-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112510002731
Analyte	2-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112510002731
Analyte	4-ABP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112510002731
Analyte	O-TOL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (11-dTXb2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112530002285
Analyte	11-DTXB2
Sample type	URINE
Result	516
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-11
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (iPF2a-III)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112540002257
Analyte	IPF2A-III
Sample type	URINE
Result	328
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-12
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:43
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (1-OHP)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05115190004645
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05115170005061
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05115170005061
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (MHBMA)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05115180000848
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:44
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Creatinine)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05115160003567
Analyte	CREATININE
Sample type	URINE
Result	121
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:46
Generated On: 20 Jul 2016 05:29:51

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Date of Visit
Data signed: (jeanellek1) 18 Jun 2015 16:46:50
Generated On: 20 Jul 2016 05:29:51

Date of Visit

16 MAR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Vital Signs
Data signed: (jeanellek1) 18 Jun 2015 16:46:50
Generated On: 20 Jul 2016 05:29:51

Were Vitals Signs assessed?

No ☒

If No, please specify the reason:

SUBJECT EARLY TERMED

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Gas Transfer
Data signed: (jeanellek1) 18 Jun 2015 16:46:49
Generated On: 20 Jul 2016 05:29:51

Was the Gas Transfer performed?

No ☒

If No, please specify the reason:

SUBJECT EARLY TERMED

Category

Position

SITTING

Time of assessment

DLCO value

KCO value

DLCO/VA value

Interpretation

If Abnormal, Clinical Significance

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lung Volume Measurements
Data signed: (jeanellek1) 18 Jun 2015 16:46:49
Generated On: 20 Jul 2016 05:29:51

Were the Lung Volume Measurements performed?

No ☒

If No, please specify the reason:

SUBJECT EARLY TERMED

Category

Position

SITTING

Time of assessment

VC value

TLC value

IC value

FRC value

Interpretation

If Abnormal, Clinical Significance

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Spirometry with a short-acting bronchodilator
Data signed: (jeanellek1) 18 Jun 2015 16:46:49
Generated On: 20 Jul 2016 05:29:51

Was the Spirometry with a short-acting bronchodilator performed?

No ☒

If No, please specify the reason:

SUBJECT EARLY TERMED

Category

With short-acting bronchodilator ☒

Position

SITTING

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Best measured FVC value

Percent of predicted FVC value

Best measured FEV1 value

Predicted FEV1 value

Percent of predicted FEV1 value

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Spirometry with a short-acting bronchodilator
Data signed: (jeanellek1) 18 Jun 2015 16:46:49
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Haematology
Data signed: (jeanellek1) 18 Jun 2015 16:46:47
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Clinical Chemistry
Data signed: (jeanellek1) 18 Jun 2015 16:46:47
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Urine analysis
Data signed: (jeanellek1) 18 Jun 2015 16:46:47
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Plasma Nicotine Sample
Data signed: (jeanellek1) 18 Jun 2015 16:46:48
Generated On: 20 Jul 2016 05:29:51

Not Done	True
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If Not Done, please specify the reason:	SUBJECT EARLY TERMED
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Date DD/MMM/YYYY	
---------------------	--

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Plasma Cotinine Sample
Data signed: (jeanellek1) 18 Jun 2015 16:46:48
Generated On: 20 Jul 2016 05:29:51

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT EARLY TERMED
---	----------------------

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

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: CoHb Blood Sample <D0> (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:47
Generated On: 20 Jul 2016 05:29:51

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT EARLY TERMED
---	----------------------

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

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: CoHb Blood Sample <D0> (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:47
Generated On: 20 Jul 2016 05:29:51

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT EARLY TERMED
---	----------------------

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

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

Time hour:min 24-hour clock	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Oxysterols
Data signed: (jeanellek1) 18 Jun 2015 16:46:49
Generated On: 20 Jul 2016 05:29:51

Not Done	True
----------	------

If Not Done, please specify the reason:	SUBJECT EARLY TERMED
---	----------------------

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: 2205
Folder: Baseline (Day 0)
Form: CO Breath Test (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:47
Generated On: 20 Jul 2016 05:29:51

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

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
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Actual Time of Assessment hour:min 24-hour clock	09:59
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Result(ppm)	7
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: CO Breath Test (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:47
Generated On: 20 Jul 2016 05:29:51

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT EARLY TERMED
---	----------------------

Scheduled Time	12:00 - 13:30 <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: 2205
Folder: Baseline (Day 0)
Form: CO Breath Test (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:47
Generated On: 20 Jul 2016 05:29:51

Assessment not done	True
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If Not Done, please specify the reason:	SUBJECT EARLY TERMED
---	----------------------

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
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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: 2205
Folder: Baseline (Day 0)
Form: CO Breath Test (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:47
Generated On: 20 Jul 2016 05:29:51

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT EARLY TERMED
---	----------------------

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
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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: 2205

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (jeanellek1) 18 Jun 2015 16:46:48

Generated On: 20 Jul 2016 05:29:51

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

16 MAR 2014

06:48

trans-3'-hydroxyc
otinine

16 MAR 2014

06:48

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (jeanellek1) 18 Jun 2015 16:46:48

Generated On: 20 Jul 2016 05:29:51

Time of caffeine tablet intake

Sample collection Not Done

True

If Not Done, please specify the reason:

SUBJECT EARLY TERMED

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: 2205

Folder: Baseline (Day 0)

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

Data signed: (jeanellek1) 18 Jun 2015 16:46:49

Generated On: 20 Jul 2016 05:29:51

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:48
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: 24 hour urine collections
Data signed: (jeanellek1) 18 Jun 2015 16:46:50
Generated On: 20 Jul 2016 05:29:51

Start Date	16 MAR 2014 DD/MMM/YYYY
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Start Time	06:20 hour:min 24-hour clock
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End Date	<hr/>
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End Time	<hr/>
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Volume	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Sample Urine Collection
Data signed: (jeanellek1) 18 Jun 2015 16:46:50
Generated On: 20 Jul 2016 05:29:51

Were samples for 24h collected?

No ☒

If No, please specify the reason:

SUBJECT EARLY TERMED

How many primary tubes were collected?

How many back up tubes were collected?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

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

Date of assessment DD/MMM/YYYY	2014 MAR 16 DD/MMM/YYYY
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Time of assessment	06:06 hour:min 24-hour clock
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Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

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 <input type="radio"/>
---	----------------------------

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?	Mild <input type="radio"/>
---	----------------------------

2. Anxious, nervous

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?	Mild <input type="radio"/>
---	----------------------------

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☒

8. Restless

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

12. Coughing

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Cough Assessment
Data signed: (jeanellek1) 18 Jun 2015 16:47:07
Generated On: 20 Jul 2016 05:29:51

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 16 DD/MMM/YYYY
Time of assessment	06:02 hour:min 24-hour clock
Assessment Status	Completed <input checked="" type="radio"/>
Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input checked="" type="radio"/>
If YES, please answer the following questions:	
First Question: Cough Impact Scale How much is your cough bothering you?	47
Second Question: Cough Intensity Scale: How intense is your cough?	Moderate <input checked="" type="radio"/>
Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Sometimes <input checked="" type="radio"/>
Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	No sputum <input checked="" type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Bio-banking (Transcriptomics)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

Was a Bio-banking sample for transcriptomics taken?

No ☒

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: 2205
Folder: Baseline (Day 0)
Form: Bio-banking (Biomarkers of exposure and risk markers)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

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

No ☒

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: 2205
Folder: Baseline (Day 0)
Form: Bio-banking (nasal epithelial collection/buccal collection)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

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

No ☒

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	201
Reported Numeric Result	201
Reference Range low	55
Reference Range high	327
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) _____

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	95
Reported Numeric Result	95
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) _____

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	196
Reported Numeric Result	196
Reference Range low	162
Reference Range high	280
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	1.7
Reported Numeric Result	1.7
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	8.0
Reported Numeric Result	8.0
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: 2205

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (jeanellek1) 18 Jun 2015 16:46:51

Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	4.0
Reported Numeric Result	4.0
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b)

Visit Name

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition


Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

Lab Test Name ALKALINE PHOSPHATASE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	61
Reported Numeric Result	61
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	127
Reported Numeric Result	127
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: 2205

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (jeanellek1) 18 Jun 2015 16:46:51

Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____


Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

Lab Test Name SERUM SODIUM

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	140
Reported Numeric Result	140
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b)

Visit Name

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition


Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

Lab Test Name SERUM POTASSIUM

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	4.4
Reported Numeric Result	4.4
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	0.3
Reported Numeric Result	0.3
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b)

Visit Name

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition


Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

Lab Test Name GGT

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	28
Reported Numeric Result	28
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b)

Visit Name

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition


Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT392

Lab Test Name CREATININE (RATE BLANKED)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	0.8
Reported Numeric Result	0.8
Reference Range low	0.5
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	30
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Reported Numeric Result	30
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Reference Range low	6
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Reference Range high	43
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Range Units	U/L
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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/>
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____


Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

Lab Test Name AST (SGOT)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	20
Reported Numeric Result	20
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	20
Reported Numeric Result	20
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) _____

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT10

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.54
Reported Numeric Result	0.54
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT100

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	31
Reported Numeric Result	31
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b)

Visit Name

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT102

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	35
Reported Numeric Result	35
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) _____

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT11

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.13
Reported Numeric Result	0.13
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.04
Reported Numeric Result	0.04
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT13

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	239
Reported Numeric Result	239
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) _____

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	51.7
Reported Numeric Result	51.7
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	38.9
Reported Numeric Result	38.9
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.2
Reported Numeric Result	7.2
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT18

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.8
Reported Numeric Result	1.8
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT19

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.5
Reported Numeric Result	0.5
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) ☐

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	49
Reported Numeric Result	49
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) _____

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	89
Reported Numeric Result	89
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	17.1
Reported Numeric Result	17.1
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT7

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.60
Reported Numeric Result	7.60
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT71

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.92
Reported Numeric Result	3.92
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.95
Reported Numeric Result	2.95
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	1.021
Reported Numeric Result	1.021
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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
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Actual Collection Date	2014 03 16
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Actual Collection Time	06:48
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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	UAT43
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Lab Test Name	UR BLOOD
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b)

Visit Name

Visit Type Scheduled ☒

Accession ID W625770

Actual Collection Date 2014 03 16

Actual Collection Time 06:48

Specimen Condition

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT49

Lab Test Name UR PROTEIN

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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/>
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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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) <input type="text"/>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT5
-------------	------

Lab Test Name	UR GLUCOSE
---------------	------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 16:46:51
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (1)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
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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	_____
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Collection time hh:mm 24 hour clock	_____
--	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (2)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
-------------------------	------------

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	
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Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (3)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
-------------------------	------------

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: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (4)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
-------------------------	------------

Analyte	27-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	27HCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	11.60
-------------------------------	-------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (5)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
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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	
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Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (6)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
-------------------------	------------

Analyte	5A,6A-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5A6AECNL
--------------	----------

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.46
-------------------------------	-------

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: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (7)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
-------------------------	------------

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	
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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: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (8)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
-------------------------	------------

Analyte	6A-HYDROXY-5A-CHOLESTAN OL
---------	-------------------------------

Analyte code	6AH5ACNL
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
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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: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (9)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
-------------------------	------------

Analyte	7-KETOCHOLESTEROL
---------	-------------------

Analyte code	7KCRL
--------------	-------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	15.43
-------------------------------	-------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (10)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
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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: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (11)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
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Analyte	7B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7BHCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
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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	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Oxysterol results (12)
Generated On: 20 Jul 2016 05:29:51

Sample Accession number	3262577039
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Analyte	CHOLESTEROL
---------	-------------

Analyte code	CHOL
--------------	------

Result	
--------	--

Result Unit	MG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	0.50
-------------------------------	------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 16:46:50
Generated On: 20 Jul 2016 05:29:51

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	No <input checked="" type="radio"/>
-------------------------------	-------------------------------------

Reason not done	SUBJECT EARLY TERMED
-----------------	----------------------

Date of assessment	<hr/>
--------------------	-------

Time of assessment	<hr/>
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How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.

If you agree or strongly agree, please describe :

2. You enjoy smoking with the device as much as without it.

If you disagree or strongly disagree, please describe :

3. The taste of the conventional cigarettes/products is different with the device.

If you agree or strongly agree, please describe :

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 16:46:50
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2205
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b)
-----------------------	-----

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	
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Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	HEMOGLOBIN A1C,VARIANT(-70)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.3
Reported Numeric Result	5.3
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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2205
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b)
-----------------------	-----

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
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Lab Test ID	RCT1684
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	29
Reported Numeric Result	29
Reference Range low	27
Reference Range high	67
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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2205
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b)
-----------------------	-----

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	
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Battery ID	SC3249
------------	--------

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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.417
Reported Numeric Result	0.417
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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

SI Numeric Result	
SI Reference Range Low	
SI Reference Range High	
SI Units	
Reported Result Type	
Alert Flag	High <input checked="" type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (4)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2205
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b)
-----------------------	-----

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	
--------------------	--


Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

Lab Test Name	APOLIPOPROTEIN A1, RAND
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (4)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	116
Reported Numeric Result	116
Reference Range low	110
Reference Range high	205
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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (4)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (5)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2205
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b)
-----------------------	-----

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

Lab Test Name	APOLIPOPROTEIN B, RAND
---------------	------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (5)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	106
Reported Numeric Result	106
Reference Range low	55
Reference Range high	140
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (5)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (6)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2205
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b)
-----------------------	-----

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	
--------------------	--


Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

Lab Test Name	FIBRINOGEN
---------------	------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (6)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	421
Reported Numeric Result	421
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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (6)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (7)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2205
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b)
-----------------------	-----

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

Lab Test Name	HOMOCYSTEINE, EDTAPL
---------------	----------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (7)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	9.08
Reported Numeric Result	9.08
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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (7)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (8)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2205
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b)
-----------------------	-----

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	
--------------------	--


Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

Lab Test Name	SICAM-1-RUO
---------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (8)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	244.0
Reported Numeric Result	244.0
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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (8)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (9)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2205
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b)
-----------------------	-----

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W625770
--------------	---------

Actual Collection Date	2014 03 16
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	
--------------------	--


Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (9)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

Test ID	
Test Status	Done 
Reported Text Result	130
Reported Numeric Result	130
Reference Range low	98
Reference Range high	202
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: 2205
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (9)
Data signed: (jeanellek1) 18 Jun 2015 16:47:08
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

Sample type	PLASMA
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112520000778
Analyte	COT
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-10
Date of Collection	2014-MAR-16
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

Urine End Day	0
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112520000778
Analyte	THCOT
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-10
Date of Collection	2014-MAR-16
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

Urine End Day	0
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112520000775
Analyte	COT
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-10
Date of Collection	2014-MAR-16
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

Urine End Day	0
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

Sample Barcode	05112520000775
Analyte	THCOT
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-10
Date of Collection	2014-MAR-16
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)
Data signed: (jeanellek1) 18 Jun 2015 16:47:13
Generated On: 20 Jul 2016 05:29:51

Urine End Day	0
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: Date of Discharge
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of Visit	16 MAR 2014 DD/MMM/YYYY
---------------	----------------------------

Discharge Time	11:38 hour:min 24-hour clock
----------------	---------------------------------

Is the subject continuing in the ambulatory period?	No <input type="radio"/>
---	--------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: Vital Signs
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

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 11:24
hour:min 24-hour clock

Pulse rate 95
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 118
mmHg

Blood Pressure (diastolic) 78
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: Advice on the risk of smoking and debriefing
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (2)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (3)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (4)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (5)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (6)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (7)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (8)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (9)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (10)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (11)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (12)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (13)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (14)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (15)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (16)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (17)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (18)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Physical Examination (19)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Discharge (Confinement)
Form: Weight
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Measurement(s) assessed?

No ☒

If No, please specify the reason:

PER PROTOCOL; NOT NEEDED

Date of Assessment

Time of assessment

Weight

BMI

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 72
beats per minute

QRS Interval 85
msec

QT Interval 365
msec

QTcB Interval 400
msec

PR Interval 149
msec

QTcF Interval 388
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: Gas Transfer
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Was the Gas Transfer performed?

No ☐

If No, please specify the reason:

PER PI; SPIROMETRY NOT
COMPLETED DUE TO
SYNCPAL EPISODE

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: 2205
Folder: Discharge (Confinement)
Form: Lung Volume Measurements
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Were the Lung Volume Measurements performed?

No ☒

If No, please specify the reason:

PER PI; SPIROMETRY NOT
COMPLETED DUE TO
SYNCOPE EPISODE

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: 2205
Folder: Discharge (Confinement)
Form: Spirometry with a short-acting bronchodilator
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Was the Spirometry with a short-acting bronchodilator performed?

No ☒

If No, please specify the reason:

PER PI; SPIROMETRY NOT
COMPLETED DUE TO
SYNCPAL EPISODE

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: Spirometry with a short-acting bronchodilator
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Predicted FEV1 value

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: 2205
Folder: Discharge (Confinement)
Form: Haematology
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

Were samples collected?

No ☒

If No, please specify the reason:

SAMPLES TAKEN FROM DAY O
VISIT

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

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: Clinical Chemistry
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

Were samples collected?

No ☒

If No, please specify the reason:

SAMPLES TAKEN FROM DAY O
VISIT

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

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: Urine analysis
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

Were samples collected?

No ☒

If No, please specify the reason:

SAMPLES TAKEN FROM DAY O
VISIT

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Discharge (Confinement)
Form: CO Breath Test
Data signed: (jeanellek1) 18 Jun 2015 16:47:14
Generated On: 20 Jul 2016 05:29:51

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	DEFERRED DUE TO ADEVERSE EVENT
---	-----------------------------------

Actual Time of Assessment	<hr/>
---------------------------	-------

Result	<hr/>
--------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Product Use
Form: Product administration-mCC
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Product Use
Form: Product administration-mCC (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	06:33
----------------------	-------

Time of butt return	06:46
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 2205
Folder: Product Use
Form: Product administration-mCC (2)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	08:09
----------------------	-------

Time of butt return	08:16
---------------------	-------

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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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: 2205
Folder: Product Use
Form: Product administration-mCC (3)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input type="radio"/>
-------	------------------------------

Type of Product Use	mCC <input type="radio"/>
---------------------	---------------------------

Time of distribution	08:45
----------------------	-------

Time of butt return	08:59
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 2205
Folder: Product Use
Form: Product administration-mCC (4)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	09:50
----------------------	-------

Time of butt return	10:17
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 2205
Folder: Product Use
Form: Product administration-mCC (5)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	12:42
----------------------	-------

Time of butt return	12:50
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 2205
Folder: Product Use
Form: Product administration-mCC (6)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	13:18
----------------------	-------

Time of butt return	13:26
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 2205
Folder: Product Use
Form: Product administration-mCC (7)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	14:18
----------------------	-------

Time of butt return	14:25
---------------------	-------

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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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: 2205
Folder: Product Use
Form: Product administration-mCC (8)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	15:33
----------------------	-------

Time of butt return	15:41
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 2205
Folder: Product Use
Form: Product administration-mCC (9)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	16:11
----------------------	-------

Time of butt return	16:22
---------------------	-------

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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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: 2205
Folder: Product Use
Form: Product administration-mCC (10)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	16:59
----------------------	-------

Time of butt return	17:04
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 2205
Folder: Product Use
Form: Product administration-mCC (11)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	18:51
----------------------	-------

Time of butt return	19:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

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: 2205
Folder: Product Use
Form: Product administration-mCC (12)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	19:33
----------------------	-------

Time of butt return	19:41
---------------------	-------

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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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: 2205
Folder: Product Use
Form: Product administration-mCC (13)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	20:18
----------------------	-------

Time of butt return	20:59
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
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Comment	<hr/>
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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: 2205
Folder: Product Use
Form: Product administration-mCC (14)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	15 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	20:59
----------------------	-------

Time of butt return	21:05
---------------------	-------

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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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: 2205
Folder: Product Use
Form: Product administration-mCC (15)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	16 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	09:59
----------------------	-------

Time of butt return	10:07
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
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Comment	PARTICIPANT DID NOT USE SODIM DEVICE DUE TO EARLY TERM
---------	--

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: 2205
Folder: Product Use
Form: Product administration-mCC (16)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	16 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	10:07
----------------------	-------

Time of butt return	10:17
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	PARTICIPANT DID NOT USE SODIM DEVICE DUE TO EARLY TERM
---------	--

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: 2205
Folder: Product Use
Form: Product administration-mCC (17)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	16 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	10:55
----------------------	-------

Time of butt return	11:02
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	PARTICIPANT DID NOT USE SODIM DEVICE DUE TO EARLY TERM
---------	--

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: 2205
Folder: Product Use
Form: Product administration-mCC (18)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	16 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	11:34
----------------------	-------

Time of butt return	<hr/>
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
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Comment	PARTICIPANT DID NOT USE SODIM DEVICE DUE TO EARLY TERM
---------	--

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: 2205
Folder: Product Use
Form: Product administration-mCC (19)
Data signed: (jeanellek1) 18 Jun 2015 16:47:17
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	16 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	10:33
----------------------	-------

Time of butt return	10:39
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	PARTICIPANT DID NOT USE SODIM DEVICE DUE TO EARLY TERM
---------	--

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: 2205
Folder: Product Use
Form: Product administration-THS menthol
Data signed: (jeanellek1) 18 Jun 2015 16:47:20
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Product Use
Form: Product administration-THS menthol (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:20
Generated On: 20 Jul 2016 05:29:51

Date of product use DD/MMM/YYYY	14 MAR 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

Time of distribution	15:40
----------------------	-------

Time of product return	15:47
------------------------	-------

SODIM device number	<hr/>
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SODIM sample holder number	<hr/>
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Tobacco plug kit number	<hr/>
-------------------------	-------

Tobacco plug vial number	<hr/>
--------------------------	-------

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B-08545
--------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (jeanellek1) 18 Jun 2015 16:47:20

Generated On: 20 Jul 2016 05:29:51

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: 2205

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (jeanellek1) 18 Jun 2015 16:47:20

Generated On: 20 Jul 2016 05:29:51

Was there any Adverse Event for this subject?

Yes ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:20
Generated On: 20 Jul 2016 05:29:51

AE Identifier	1
---------------	---

Adverse Event	ABRASION TO FOREHEAD
---------------	----------------------

Start Date	16 MAR 2014
------------	-------------

DD/MMM/YYYY

End Date	18 MAR 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Related <input type="radio"/>
-------------------------------	-------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (jeanellek1) 18 Jun 2015 16:47:20

Generated On: 20 Jul 2016 05:29:51

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (jeanellek1) 18 Jun 2015 16:47:20
Generated On: 20 Jul 2016 05:29:51

AE Identifier	2
---------------	---

Adverse Event	ABRASION TO NOSE
---------------	------------------

Start Date	16 MAR 2014
------------	-------------

DD/MMM/YYYY

End Date	18 MAR 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Related <input type="radio"/>
-------------------------------	-------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (jeanellek1) 18 Jun 2015 16:47:20
Generated On: 20 Jul 2016 05:29:51

Action taken with study product None ☒

Other action taken ☐

Outcome Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (jeanellek1) 18 Jun 2015 16:47:20
Generated On: 20 Jul 2016 05:29:51

AE Identifier	3
---------------	---

Adverse Event	EPISTAXIS DUE TO FALL
---------------	-----------------------

Start Date	16 MAR 2014
------------	-------------

DD/MMM/YYYY

End Date	16 MAR 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria	<hr/>
----------------------	-------

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Related <input type="radio"/>
-------------------------------	-------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness	<hr/>
-----------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (jeanellek1) 18 Jun 2015 16:47:20

Generated On: 20 Jul 2016 05:29:51

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (jeanellek1) 18 Jun 2015 16:47:20
Generated On: 20 Jul 2016 05:29:51

AE Identifier	4
---------------	---

Adverse Event	SYNCPAL EPISODE DUE TO SPIROMETRY
---------------	-----------------------------------

Start Date	16 MAR 2014
------------	-------------

DD/MMM/YYYY

End Date	16 MAR 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Moderate Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Related <input type="radio"/>
-------------------------------	-------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (jeanellek1) 18 Jun 2015 16:47:20
Generated On: 20 Jul 2016 05:29:51

Action taken with study product	Product use Stopped <input checked="" type="radio"/>
---------------------------------	--

Other action taken	SUBJECT WAS DISCONTINUED FROM STUDY
--------------------	--

Outcome	Recovered or Resolved <input checked="" type="radio"/>
---------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Previous and Concomitant Medication
Form: Previous and Concomitant Medication Y/N
Data signed: (jeanellek1) 18 Jun 2015 16:47:21
Generated On: 20 Jul 2016 05:29:51

Has the subject taken previous or concomitant
medication?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Device Events
Form: Device report - THS 2.2 menthol Cigarette Holder
Data signed: (jeanellek1) 18 Jun 2015 16:47:21
Generated On: 20 Jul 2016 05:29:51

Were there any events with the device?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Device Events
Form: Device report - THS 2.2 menthol Cigarette Holder (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:21
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Device Events
Form: Device report - THS 2.2 menthol Cigarette Holder (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:21
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Device Events
Form: Device report - THS 2.2 menthol Charging Unit
Data signed: (jeanellek1) 18 Jun 2015 16:47:21
Generated On: 20 Jul 2016 05:29:51

Were there any events with the device?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Device Events
Form: Device report - THS 2.2 menthol Charging Unit (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:21
Generated On: 20 Jul 2016 05:29:51

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: 2205
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Form: Device report - THS 2.2 menthol Charging Unit (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:21
Generated On: 20 Jul 2016 05:29:51

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: 2205
Folder: Device Inventory
Form: Device Inventory - THS 2.2 menthol Cigarette Holder (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:21
Generated On: 20 Jul 2016 05:29:51

Device Inventory	1
Log Number	

Date of Device Distribution	14 MAR 2014
DD/MMM/YYYY	

Time of	15:40
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
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Device Serial Number	1245432
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Date of Device Collection	14 MAR 2014
DD/MMM/YYYY	

Time of	15:47
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Device Inventory
Form: Device Inventory - THS 2.2 menthol Charging Unit (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:21
Generated On: 20 Jul 2016 05:29:51

Device Inventory	1
Log Number	

Date of Device Distribution	14 MAR 2014
DD/MMM/YYYY	

Time of	15:40
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
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Device Serial Number	1318242
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Date of Device Collection	14 MAR 2014
DD/MMM/YYYY	

Time of	15:47
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205

Folder: Unscheduled Visit

Form: Vital Signs

Data signed: (jeanellek1) 18 Jun 2015 16:47:22

Generated On: 20 Jul 2016 05:29:51

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
16 MAR 2014	07:53	No	88	18	120	88	Supine
16 MAR 2014	07:55	No	89	20	120	88	Sitting
16 MAR 2014	07:55	No	85	20	118	78	Sitting

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Folder: Unscheduled Visit
Form: ECG (12-Lead Standard) (1)
Data signed: (jeanellek1) 18 Jun 2015 16:47:22
Generated On: 20 Jul 2016 05:29:51

Date of assessment DD/MMM/YYYY	16 MAR 2014
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Position	Supine <input checked="" type="radio"/>
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Heart Rate (beats per minute)	72
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QRS Interval (msec)	85
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QT Interval (msec)	365
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QTcB Interval (msec)	400
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QTcF Interval	388 msec
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PR Interval (msec)	149
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Interpretation	Normal <input checked="" type="radio"/>
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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: 2205
Form: End of study
Data signed: (jeanellek1) 18 Jun 2015 16:46:21
Generated On: 20 Jul 2016 05:29:51

End of study date	13 APR 2014 DD/MMM/YYYY
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Has the subject completed the study ?	No <input checked="" type="radio"/>
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If No, please specify the reason:	Adverse Events <input checked="" type="radio"/>
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Details:	SUBJECT EXPERIENCED AN SYNCOPE EPISODE AFTER SPIROMETRY PROCEDURE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2205
Form: Consent Withdrawal
Data signed: (jeanellek1) 18 Jun 2015 16:46:21
Generated On: 20 Jul 2016 05:29:51

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
