

Subject Case Report Forms

2146 (Prod: Covance Clinical Development Services, Dallas, Texas)

Generated On: 20 Jul 2016 01:42:19

All time stamps listed in this document are displayed in GMT

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Subject
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Screening number	2146
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Site number	DAL
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Subject Status

Form: Subject Status

Data signed: (jeanellek1) 18 Jun 2015 14:51:16

Generated On: 20 Jul 2016 01:42:19

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

27 FEB 2014
DD/MMM/YYYY

Randomization Time

13:17
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:51:19

Generated On: 20 Jul 2016 01:42:19

Date of Visit

07 FEB 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Additional Informed Consent
Data signed: (jeanellek1) 18 Jun 2015 14:51:16
Generated On: 20 Jul 2016 01:42:19

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

Yes ☒

Consent Date

07 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

07 FEB 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Inclusion Criteria

Data signed: (jeanellek1) 18 Jun 2015 14:51:17

Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Inclusion Criteria (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Inclusion Criteria (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Inclusion Criterion Number	2
Inclusion Criterion	Subject is at a minimum 22 years of age(inclusive). <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: 2146
Folder: Screening
Form: Inclusion Criteria (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Inclusion Criteria (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Inclusion Criterion Number	4
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Inclusion Criterion	Subject smokes at least 10 commercially available mCCs per day (no brand restrictions), for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).
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Result	Yes
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*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Inclusion Criteria (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Inclusion Criteria (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Inclusion Criterion Number	6
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Inclusion Criterion	The subject is ready to comply with study protocol (e.g readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol).
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Result	Yes
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*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Exclusion Criteria

Data signed: (jeanellek1) 18 Jun 2015 14:51:17

Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Exclusion Criteria (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Exclusion Criteria (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Exclusion Criteria (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (jeanellek1) 18 Jun 2015 14:51:17

Generated On: 20 Jul 2016 01:42:19

Exclusion Criterion Number	4
Exclusion Criterion	Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013).
Result	No
*If any has been answered Yes, subject must not be included in the study.	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Exclusion Criteria (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Exclusion Criteria (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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
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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: 2146
Folder: Screening
Form: Exclusion Criteria (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Exclusion Criterion Number	7
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Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m ² .	<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: 2146
Folder: Screening
Form: Exclusion Criteria (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Exclusion Criteria (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Exclusion Criteria (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Exclusion Criteria (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Exclusion Criteria (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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 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: 2146
Folder: Screening
Form: Exclusion Criteria (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Exclusion Criterion Number	14
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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.
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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: 2146
Folder: Screening
Form: Exclusion Criteria (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (jeanellek1) 18 Jun 2015 14:51:17

Generated On: 20 Jul 2016 01:42:19

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
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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: 2146
Folder: Screening
Form: Exclusion Criteria (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Exclusion Criteria (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Exclusion Criterion Number	18
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Exclusion Criterion	The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).
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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: 2146
Folder: Screening
Form: Exclusion Criteria (18)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Exclusion Criteria (19)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Exclusion Criteria (20)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Exclusion Criterion Number	21
Exclusion Criterion	For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding. <input type="radio"/>
Result	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: 2146
Folder: Screening
Form: Exclusion Criteria (21)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Exclusion Criterion Number	22
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Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception
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Result	NA
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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: 2146
Folder: Screening
Form: Demographics
Data signed: (jeanellek1) 18 Jun 2015 14:51:16
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Sex	Male <input checked="" type="radio"/>
Race	Other <input checked="" type="radio"/>
Other, specify	WHITE AND NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
Ethnicity	Not Hispanic <input checked="" type="radio"/>
Date the Subject signed the Informed Consent	07 FEB 2014 DD/MMM/YYYY
Time the Subject signed the Informed Consent	11:46 hour:min 24-hour clock
Age(Derived)	22

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Medical History/Concomitant Disease
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Date of collection

07 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: 2146
Folder: Screening
Form: Medical History/Concomitant Disease (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Date of collection	07 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: 2146
Folder: Screening
Form: Vital Signs<Screening/<
Data signed: (jeanellek1) 18 Jun 2015 14:51:19
Generated On: 20 Jul 2016 01:42:19

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 07 FEB 2014
DD/MMM/YYYY

Time of assessment 12:38
hour:min 24-hour clock

Pulse rate 60
beats per minute

Respiratory rate 14
breaths per minute

Blood Pressure (systolic) 107
mmHg

Blood Pressure (diastolic) 96
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Physical Examination
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 FEB 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Physical Examination (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (18)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Physical Examination (19)
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 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: 2146
Folder: Screening
Form: Advice on the risk of smoking and debriefing
Data signed: (jeanellek1) 18 Jun 2015 14:51:19
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Identification of Current Cigarette Brand
Data signed: (jeanellek1) 18 Jun 2015 14:51:19
Generated On: 20 Jul 2016 01:42:19

Date	07 FEB 2014 DD/MMM/YYYY
------	----------------------------

Brand name	MARLBORO MENTHOL 100'S
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (jeanellek1) 18 Jun 2015 14:51:19

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Smoking History
Data signed: (jeanellek1) 18 Jun 2015 14:51:19
Generated On: 20 Jul 2016 01:42:19

Date of Assessment

07 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?

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: 2146
Folder: Screening
Form: Weight and Height
Data signed: (jeanellek1) 18 Jun 2015 14:51:19
Generated On: 20 Jul 2016 01:42:19

Measurement(s) assessed? Yes ☒

If No, please specify the reason: _____

Date of assessment 07 FEB 2014
DD/MMM/YYYY

Weight 98.6
kg

Height 175.5
cm

BMI (Derived) 32.0
kg/m2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 14:51:16
Generated On: 20 Jul 2016 01:42:19

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 07 FEB 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 65
beats per minute

QRS Interval 101
msec

QT Interval 371
msec

QTcB Interval 387
msec

QTcF Interval 381
msec

PR Interval 143
msec

Interpretation Normal ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 14:51:16
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Spirometry (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:19
Generated On: 20 Jul 2016 01:42:19

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Position SITTING

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

Date of assessment DD/MMM/YYYY 07 FEB 2014

Time of assessment 16:04

Predicted FVC value 5.45 L

Best measured FVC value 6.03 L

Percent of predicted FVC value 110 %

Best measured FEV1 value 4.52 L

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Spirometry (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:19

Generated On: 20 Jul 2016 01:42:19

Predicted FEV1 value	4.53 L
Percent of predicted FEV1 value	99 %
Calculated ratio between FEV1/FVC	0.75
MEF 25/75 value	3.57 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: 2146
Folder: Screening
Form: Spirometry (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:19
Generated On: 20 Jul 2016 01:42:19

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Position SITTING

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

Date of assessment DD/MMM/YYYY 07 FEB 2014

Time of assessment 16:29

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 5.45 L

Best measured FVC value 6.02 L

Percent of predicted FVC value 110 %

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Spirometry (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:19
Generated On: 20 Jul 2016 01:42:19

Best measured FEV1 value	4.67 L
Predicted FEV1 value	4.53 L
Percent of predicted FEV1 value	103 %
Calculated ratio between FEV1/FVC	0.78
MEF 25/75 value	4.31 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: 2146

Folder: Screening

Form: Chest X-Ray

Data signed: (jeanellek1) 18 Jun 2015 14:51:20

Generated On: 20 Jul 2016 01:42:19

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

10 FEB 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Haematology
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Clinical Chemistry
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Urine analysis
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Screening
Form: Serology for HIV and Hepatitis B and C
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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

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

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Urine Drug Screen

Data signed: (jeanellek1) 18 Jun 2015 14:51:17

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date of sample collection	07 FEB 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	11:56 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (jeanellek1) 18 Jun 2015 14:51:17

Generated On: 20 Jul 2016 01:42:19

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Alcohol Test

Data signed: (jeanellek1) 18 Jun 2015 14:51:17

Generated On: 20 Jul 2016 01:42:19

Was the alcohol test performed?

Yes ☒

If No, please specify the reason: _____

Method used

Breath test ☒

Date of assessment

07 FEB 2014
DD/MMM/YYYY

Time of assessment

12:15
hour:min 24-hour clock

Result

Negative ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Urine Cotinine Test
Data signed: (jeanellek1) 18 Jun 2015 14:51:17
Generated On: 20 Jul 2016 01:42:19

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	07 FEB 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	11:56 hour:min 24-hour clock
---------------------------	---------------------------------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp CHEMISTRY(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

07 FEB 2014

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp CHEMISTRY(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	GLUCOSE, SERUM
Code	001032
Result	66
Unit	MG/DL
Lower limit	65
Upper limit	99
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp CHEMISTRY(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	BUN
Code	001040
Result	12
Unit	MG/DL
Lower limit	6
Upper limit	20
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	CHOLESTEROL, TOTAL
Code	001065
Result	152
Unit	MG/DL
Lower limit	100
Upper limit	189
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	PROTEIN, TOTAL, SERUM
Code	001073
Result	6.4
Unit	G/DL
Lower limit	6.0
Upper limit	8.5
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (jeanellek1) 18 Jun 2015 14:51:20

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	ALBUMIN, SERUM
Code	001081
Result	4.4
Unit	G/DL
Lower limit	3.5
Upper limit	5.5
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (jeanellek1) 18 Jun 2015 14:51:20

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	BILIRUBIN, TOTAL
Code	001099
Result	0.2
Unit	MG/DL
Lower limit	0.0
Upper limit	1.2
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	ALKALINE PHOSPHATASE, S
Code	001107
Result	67
Unit	IU/L
Lower limit	39
Upper limit	117
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	LDH
Code	001115
Result	132
Unit	IU/L
Lower limit	0
Upper limit	225
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	AST (SGOT)
Code	001123
Result	18
Unit	IU/L
Lower limit	0
Upper limit	40
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	TRIGLYCERIDES
Code	001172
Result	64
Unit	MG/DL
Lower limit	0
Upper limit	114
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	POTASSIUM, SERUM
Code	001180
Result	3.9
Unit	MMOL/L
Lower limit	3.5
Upper limit	5.2
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	SODIUM, SERUM
Code	001198
Result	136
Unit	MMOL/L
Lower limit	134
Upper limit	144
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
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: 2146

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (jeanellek1) 18 Jun 2015 14:51:20

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	CREATININE, SERUM
Code	001370
Result	0.82
Unit	MG/DL
Lower limit	0.76
Upper limit	1.27
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	ALT (SGPT)
Code	001545
Result	19
Unit	IU/L
Lower limit	0
Upper limit	44
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	GGT
Code	001958
Result	19
Unit	IU/L
Lower limit	0
Upper limit	65
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	HEP C VIRUS AB
Code	140683
Result	0.1
Unit	S/CO RATIO
Lower limit	0.0
Upper limit	0.9
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:20
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp SEROLOGY(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

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

Date of Sample Collection YYYY/MM/DD	07 FEB 2014
---	-------------

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp SEROLOGY(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

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

Date of Sample Collection YYYY/MM/DD	07 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	13:23
---------------------------	-------

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

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

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

Unit	
------	--

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

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

Flag	
------	--

Clinically Significant?	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp SEROLOGY(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	SEROLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	HBSAG SCREEN
Code	006510
Result	NEGATIVE
Unit	
Lower limit	NEGATIVE
Upper limit	
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	SEROLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
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: 2146

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:21

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp HEMATOLOGY(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

07 FEB 2014

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp HEMATOLOGY(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	WBC
Code	005025
Result	6.5
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp HEMATOLOGY(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	RBC
Code	005033
Result	4.86
Unit	X10E6/UL
Lower limit	4.14
Upper limit	5.80
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:21

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	HEMOGLOBIN
Code	005041
Result	14.9
Unit	G/DL
Lower limit	12.6
Upper limit	17.7
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	HEMATOCRIT
Code	005058
Result	44.9
Unit	%
Lower limit	37.5
Upper limit	51.0
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	MCV
Code	015065
Result	92
Unit	FL
Lower limit	79
Upper limit	97
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (jeanellek1) 18 Jun 2015 14:51:21

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	MCH
Code	015073
Result	30.7
Unit	PG
Lower limit	26.6
Upper limit	33.0
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (jeanellek1) 18 Jun 2015 14:51:21

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	MCHC
Code	015081
Result	33.2
Unit	G/DL
Lower limit	31.5
Upper limit	35.7
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	NEUTROPHILS
Code	015107
Result	56
Unit	%
Lower limit	40
Upper limit	74
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	LYMPHS
Code	015123
Result	36
Unit	%
Lower limit	14
Upper limit	46
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (jeanellek1) 18 Jun 2015 14:51:21

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	MONOCYTES
Code	015131
Result	7
Unit	%
Lower limit	4
Upper limit	12
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (jeanellek1) 18 Jun 2015 14:51:21

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
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: 2146
Folder: Screening
Form: Lab-BU-LabCorp (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
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: 2146
Folder: Screening
Form: Lab-BU-LabCorp (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	PLATELETS
Code	015172
Result	221
Unit	X10E3/UL
Lower limit	155
Upper limit	379
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	NEUTROPHILS (ABSOLUTE)
Code	015909
Result	3.6
Unit	X10E3/UL
Lower limit	1.4
Upper limit	7.0
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (jeanellek1) 18 Jun 2015 14:51:21

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	LYMPHS (ABSOLUTE)
Code	015917
Result	2.4
Unit	X10E3/UL
Lower limit	0.7
Upper limit	3.1
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
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: 2146
Folder: Screening
Form: Lab-BU-LabCorp (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
Analyte Name	EOS (ABSOLUTE)
Code	015933
Result	0.1
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.4
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (18)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:23
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: 2146
Folder: Screening
Form: Lab-BU-LabCorp (18)
Data signed: (jeanellek1) 18 Jun 2015 14:51:21
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp URINALYSIS(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

07 FEB 2014

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp URINALYSIS(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:56
Analyte Name	SPECIFIC GRAVITY
Code	013060
Result	1.015
Unit	
Lower limit	1.005
Upper limit	1.030
Flag	
Clinically Significant?	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp URINALYSIS(07 FEB 2014)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:56
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: 2146
Folder: Screening
Form: Lab-BU-LabCorp (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:56
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: 2146
Folder: Screening
Form: Lab-BU-LabCorp (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:56
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: 2146

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (jeanellek1) 18 Jun 2015 14:51:22

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:56
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: 2146
Folder: Screening
Form: Lab-BU-LabCorp (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:56
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: 2146

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (jeanellek1) 18 Jun 2015 14:51:22

Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	07 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:56
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: 2146
Folder: Screening
Form: Lab-BU-LabCorp (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:22
Generated On: 20 Jul 2016 01:42:19

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number 03896700040

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Screening
Form: FTND Questionnaire
Generated On: 20 Jul 2016 01:42:19

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

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

Date of assessment	2014 FEB 07
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	14:48
	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?	6-30 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?	Any other <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?	Yes <input checked="" type="radio"/>
---	--------------------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Screening

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:19

Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 07 FEB 2014
DD/MMM/YYYY

Time of assessment 11:52
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: 2146

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:51:25

Generated On: 20 Jul 2016 01:42:19

Date of Visit

25 FEB 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Admission (Day -2)
Form: Inclusion Criteria
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Admission (Day -2)
Form: Inclusion Criteria (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Inclusion Criteria (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:23

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Inclusion Criteria (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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"/>
---------------------	--	----------------------------------

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: 2146
Folder: Admission (Day -2)
Form: Exclusion Criteria
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:23

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Exclusion Criteria (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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.
---------------------	---

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: 2146

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:23

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Exclusion Criteria (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (jeanellek1) 18 Jun 2015 14:51:23

Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (jeanellek1) 18 Jun 2015 14:51:23

Generated On: 20 Jul 2016 01:42:19

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.
---------------------	---

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: 2146

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (jeanellek1) 18 Jun 2015 14:51:23

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Exclusion Criteria (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (jeanellek1) 18 Jun 2015 14:51:23

Generated On: 20 Jul 2016 01:42:19

Exclusion Criterion Number	13
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Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.
---------------------	---

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Admission (Day -2)
Form: Exclusion Criteria (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Exclusion Criteria (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Exclusion Criteria (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Exclusion Criteria (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Exclusion Criteria (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Vital Signs
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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 15:05
hour:min 24-hour clock

Pulse rate 86
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 128
mmHg

Blood Pressure (diastolic) 71
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Admission (Day -2)
Form: Product preference
Data signed: (jeanellek1) 18 Jun 2015 14:51:24
Generated On: 20 Jul 2016 01:42:19

Which Product Arm would you prefer to be randomized
to:

mCC ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Admission (Day -2)
Form: Advice on the risk of smoking and debriefing
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Admission (Day -2)
Form: Physical Examination (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (18)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Physical Examination (19)
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Identification of Current Cigarette Brand
Data signed: (jeanellek1) 18 Jun 2015 14:51:24
Generated On: 20 Jul 2016 01:42:19

Brand name

MARLBORO MENTHOL 100'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Admission (Day -2)
Form: THS 2.2 menthol product test
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Smoking History
Data signed: (jeanellek1) 18 Jun 2015 14:51:24
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Admission (Day -2)
Form: Weight
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

Measurement(s) assessed? Yes ☒

If No, please specify the reason: _____

Time of assessment 14:57
hour:min 24-hour clock

Weight 98.6
kg

Waist circumference 105
cm

BMI 32.0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (jeanellek1) 18 Jun 2015 14:51:23

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Time of sample collection	14:33
	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: 2146

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (jeanellek1) 18 Jun 2015 14:51:23

Generated On: 20 Jul 2016 01:42:19

Drug type	Result
Opiates	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Admission (Day -2)
Form: Alcohol Test
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 14:28
hour:min 24-hour clock

Result Negative ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Admission (Day -2)
Form: CO Breath Test
Data signed: (jeanellek1) 18 Jun 2015 14:51:23
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	14:28
	hour:min 24-hour clock

Result	21
	ppm

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Admission (Day -2)

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:24

Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 25 FEB 2014
DD/MMM/YYYY

Time of assessment 15:14
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: 2146

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:51:26

Generated On: 20 Jul 2016 01:42:19

Date of Visit

26 FEB 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Vital Signs
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 10:12
hour:min 24-hour clock

Pulse rate 61
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 117
mmHg

Blood Pressure (diastolic) 66
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (jeanellek1) 18 Jun 2015 14:51:25

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	26 FEB 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:33
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:25

Generated On: 20 Jul 2016 01:42:19

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	06:32
---	-------

Result(ppm)	09
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:25

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:24
---	-------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:25

Generated On: 20 Jul 2016 01:42:19

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	16:18
---	-------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (jeanellek1) 18 Jun 2015 14:51:25

Generated On: 20 Jul 2016 01:42:19

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	20:18
---	-------

Result(ppm)	17
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: 4 hour urine collection
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

Start Time	09:59 hour:min 24-hour clock
<hr/>	
End Time	14:01 hour:min 24-hour clock
<hr/>	
Volume	661 mL
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Sample Urine Collection (4 Hour collection)
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003537
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	5.90
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	-1
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-26
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 FEB 26 DD/MMM/YYYY
Time of assessment	20:07 hour:min 24-hour clock
Assessment Status	Completed
1. Was smoking satisfying?	Quite a lot
2. Did cigarettes taste good?	A lot
3. Did you enjoy the sensation in your throat and chest?	Moderately
4. Did smoking calm you down?	Moderately
5. Did smoking make you feel more awake?	Moderately
6. Did smoking make you feel less irritable?	A lot
7. Did smoking help you concentrate?	Moderately
8. Did smoking reduce your hunger for food?	Moderately

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

9. Did smoking make you dizzy? Little ☐

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

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

12. Did you enjoy smoking? Quite a lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Behavioral Risk Factor Surveillance System Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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

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

Date of assessment	26 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Do you now smoke cigarettes every day, some days, or not at all?	Every day <input checked="" type="radio"/>
--	--

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?	<hr/>
--	-------

How long has it been since you last smoked a cigarette, even one or two puffs?	<hr/>
--	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Behavioral Risk Factor Surveillance System Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

Do you currently use chewing tobacco, snuff, or snus
every day, some days, or not at all?

Not at all ☒

NOTE: Snus (Swedish for snuff) is a moist smokeless
tobacco, usually sold in small pouches that are placed
under the lip against the gum.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	26 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:28 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	14 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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	26 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:28 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	14 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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

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

Time _____ Currently (last 3 months) ☒

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

Manufactured Cigarettes 12
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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	26 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:28 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	14 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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

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

Time _____ 1 year ago ☒

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

Manufactured Cigarettes _____ 10
per day

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

Hand-rolled Cigarettes _____
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	26 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:28 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?	14 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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

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

Time _____ 5 years ago ☒

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

Manufactured Cigarettes _____ 05
per day

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

Hand-rolled Cigarettes _____
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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

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

Reason not done	
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Date of assessment	26 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:28 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?	14 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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

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

Time _____ 10 years ago ☒

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

Manufactured Cigarettes
per day _____

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

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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

Was paper questionnaire used?	Yes <input type="radio"/>
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Reason not done	<hr/>
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Date of assessment	26 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:28 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 type="radio"/>
--	---

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	14 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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

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

Time 15 years ago ☒

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

Manufactured Cigarettes
per day _____

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

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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

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

Reason not done	<hr/>
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Date of assessment	26 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:28 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	14 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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

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

Time 20 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day? 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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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

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

Reason not done	<hr/>
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Date of assessment	26 FEB 2014 DD/MMM/YYYY
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Time of assessment	20:28 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	14 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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

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

Time _____ More than 20 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day? _____ 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: 2146
Folder: Baseline (Day -1)
Form: Smoking Questionnaire (SQ) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:25
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day -1)
Form: Supplemental Questions
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 26 FEB 2014
DD/MMM/YYYY

Time of assessment 20:31

1. How long it takes for the subject to complete the SQ 2 minutes

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Supplemental Questions (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 26 FEB 2014
DD/MMM/YYYY

Time of assessment 20:31

1. How long it takes for the subject to complete the SQ 2 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: 2146
Folder: Baseline (Day -1)
Form: Supplemental Questions (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 26 FEB 2014
DD/MMM/YYYY

Time of assessment 20:31

1. How long it takes for the subject to complete the SQ 2 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: 2146
Folder: Baseline (Day -1)
Form: Supplemental Questions (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 26 FEB 2014
DD/MMM/YYYY

Time of assessment 20:31

1. How long it takes for the subject to complete the SQ 2 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: 2146
Folder: Baseline (Day -1)
Form: Supplemental Questions (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 26 FEB 2014
DD/MMM/YYYY

Time of assessment 20:31

1. How long it takes for the subject to complete the SQ 2 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: 2146
Folder: Baseline (Day -1)
Form: Supplemental Questions (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 26 FEB 2014
DD/MMM/YYYY

Time of assessment 20:31

1. How long it takes for the subject to complete the SQ 2 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Supplemental Questions (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:26
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 26 FEB 2014
DD/MMM/YYYY

Time of assessment 20:31

1. How long it takes for the subject to complete the SQ 2 minutes

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Questionnaire on smoking urges (QSU)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 FEB 26
DD/MMM/YYYY	
Time of assessment	20:06
hour:min 24-hour clock	
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Do not agree or disagree <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	Do not agree or disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Somewhat disagree <input type="radio"/>
5. All I want right now is a cigarette	Somewhat disagree <input type="radio"/>
6. I have an urge for a cigarette	Somewhat 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: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003706
Analyte	HPMA
Sample type	URINE
Result	473
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003706
Analyte	CEMA
Sample type	URINE
Result	57.3
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003706
Analyte	HBMA
Sample type	URINE
Result	144
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004451
Analyte	NNAL
Sample type	URINE
Result	112
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004451
Analyte	NNN
Sample type	URINE
Result	7.56
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (HEMA)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (HEMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112470002225
Analyte	HEMA
Sample type	URINE
Result	1.47
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-05
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (HEMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

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

(1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000815
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Analyte	COT
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Sample type	URINE
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Result	1120
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-06
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Date of Collection	2014-FEB-26
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Timepoint-minutes	
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

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

(2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000815
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Analyte	COT-GLUC
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Sample type	URINE
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Result	3550
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Result Unit	NG/ML
-------------	-------

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

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

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-FEB-26
--------------------	-------------

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000815
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Analyte	NIC
---------	-----

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

Result	96.0
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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	AA99128-06
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Date of Collection	2014-FEB-26
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Timepoint-minutes	
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

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

(4)

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000815
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Analyte	NIC-GLUC
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Sample type	URINE
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Result	631
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-06
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Date of Collection	2014-FEB-26
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Timepoint-minutes	
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

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

(5)

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000815
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Analyte	THCOT
---------	-------

Sample type	URINE
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Result	1740
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-06
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Date of Collection	2014-FEB-26
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Timepoint-minutes	
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Urine Start Day	
-----------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000815
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Analyte	THCOT-GLUC
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Sample type	URINE
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Result	651
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-06
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Date of Collection	2014-FEB-26
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
-----------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day -1)

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

(6)

Data signed: (jeanellek1) 18 Jun 2015 14:51:27

Generated On: 20 Jul 2016 01:42:19

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (3-OH BaP)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112490002225
Analyte	3-OH BAP
Sample type	URINE
Result	36.8
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-07
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002247
Analyte	1-NA
Sample type	URINE
Result	49.7
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002247
Analyte	2-NA
Sample type	URINE
Result	12.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002247
Analyte	4-ABP
Sample type	URINE
Result	7.69
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002247
Analyte	O-TOL
Sample type	URINE
Result	63.9
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (11-dTXb2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112530001627
Analyte	11-DTXB2
Sample type	URINE
Result	217
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-11
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (iPF2a-III)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112540001697
Analyte	IPF2A-III
Sample type	URINE
Result	252
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-12
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (1-OHP)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115190004139
Analyte	1-OHP
Sample type	URINE
Result	53.7
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99598-03
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004137
Analyte	SBMA
Sample type	URINE
Result	0.633
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004137
Analyte	SPMA
Sample type	URINE
Result	0.949
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (MHBMA)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115180004139
Analyte	MHBMA
Sample type	URINE
Result	0.922
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	
Celerion Study Number	AA99598-02
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:27
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Creatinine)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115160002203
Analyte	CREATININE
Sample type	URINE
Result	55.6
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-14
Date of Collection	2014-FEB-26
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day -1)
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Urine End Day	-1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Date of Visit
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Date of Visit

27 FEB 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Randomization
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Randomization number (4 digits)	1047
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Allocation Arm	THS 2.2 menthol <input checked="" type="radio"/>
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Cigarette Consumption	10 – 19 conventional menthol cigarettesper day <input checked="" type="radio"/>
-----------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Vital Signs
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 10:22
hour:min 24-hour clock

Pulse rate 77
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 114
mmHg

Blood Pressure (diastolic) 67
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Gas Transfer
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Was the Gas Transfer performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 08:31

DLCO value 29.32
ml/min/mmHg

KCO value 1.34
mmol/min/kPa/L

DLCO/VA value 1.34
mL/min/mmHg/L

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lung Volume Measurements
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 08:37

VC value 6.2
L

TLC value 8.09
L

IC value 5.9
L

FRC value 2.19
L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

If Not Clinically Significant or Clinically Significant, Please DECREASED FRC AND
specify the finding(s) INCREASED RV

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Spirometry with a short-acting bronchodilator
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

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

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Position SITTING

Time of assessment 09:09

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 5.45 L

Best measured FVC value 6.1 L

Percent of predicted FVC value 111 %

Best measured FEV1 value 4.63 L

Predicted FEV1 value 4.53 L

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Spirometry with a short-acting bronchodilator
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Percent of predicted FEV1 value	102 %
---------------------------------	----------

Calculated ratio between FEV1/FVC	_____
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MEF 25/75 value	3.89 L/s
-----------------	-------------

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

If Abnormal, Clinical Significance	_____
------------------------------------	-------

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: 2146
Folder: Baseline (Day 0)
Form: Haematology
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Were samples collected? Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection? No ☒

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Clinical Chemistry
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Were samples collected? Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection? No ☒

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Urine analysis
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Plasma Nicotine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

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

Date DD/MMM/YYYY	27 FEB 2014
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Time hour:min 24-hour clock	20:53
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Plasma Cotinine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 FEB 2014
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Time hour:min 24-hour clock	20:53
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: CoHb Blood Sample <D0> (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 FEB 2014
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Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	05:44
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: CoHb Blood Sample <D0> (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 FEB 2014
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Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
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Time hour:min 24-hour clock	20:53
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Oxysterols
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?	No <input checked="" type="radio"/>
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Date DD/MMM/YYYY	27 FEB 2014
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Time hour:min 24-hour clock	05:44
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: CO Breath Test (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Assessment not done	False
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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	09:15
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Result(ppm)	12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: CO Breath Test (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Assessment not done	False
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If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
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Actual Time of Assessment hour:min 24-hour clock	12:21
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Result(ppm)	12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: CO Breath Test (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Assessment not done	False
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If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
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Actual Time of Assessment hour:min 24-hour clock	16:19
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Result(ppm)	16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: CO Breath Test (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:28
Generated On: 20 Jul 2016 01:42:19

Assessment not done	False
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If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
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Actual Time of Assessment hour:min 24-hour clock	20:18
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Result(ppm)	22
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (jeanellek1) 18 Jun 2015 14:51:28

Generated On: 20 Jul 2016 01:42:19

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

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

27 FEB 2014

05:44

trans-3'-hydroxyc
otinine

27 FEB 2014

05:44

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (jeanellek1) 18 Jun 2015 14:51:28

Generated On: 20 Jul 2016 01:42:19

Time of caffeine tablet intake	10:16
	hour:min 24-hour clock

Sample collection Not Done	False
----------------------------	-------

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
27 FEB 2014	16:16	Caffeine
27 FEB 2014	16:16	Paraxanthine

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

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 14:51:28

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 FEB 2014
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Time hour:min 24-hour clock	05:44
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: 24 hour urine collections
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Start Date	27 FEB 2014 DD/MMM/YYYY
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Start Time	06:27 hour:min 24-hour clock
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End Date	28 FEB 2014 DD/MMM/YYYY
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End Time	06:28 hour:min 24-hour clock
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Volume	1099 mL
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Sample Urine Collection
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Were samples for 24h collected? Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected? 13

How many back up tubes were collected? 13

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 27
DD/MMM/YYYY

Time of assessment

06:33
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Mild ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Mild ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Mild ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☒

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

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

13. Dreaming or nightmares

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

14. Nausea

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

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Cough Assessment
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 27
DD/MMM/YYYY

Time of assessment

06:32
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Bio-banking (Transcriptomics)
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

05:44
hour:min 24-hour clock

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

No ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Bio-banking (Biomarkers of exposure and risk markers)
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

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

Yes ☒

Time of Sample Collection

05:44
hour:min 24-hour clock

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

No ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Bio-banking (nasal epithelial collection/buccal collection)
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

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

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

Time of Nasal Epithelial Collection 15:09
hour:min 24-hour clock

Was the subject fasting for at least 30 minutes at time of sample collection? Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	139
Reported Numeric Result	139
Reference Range low	44
Reference Range high	249
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	92
Reported Numeric Result	92
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	RC272
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Battery Name	TOTAL CHOLESTEROL
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Lab Test ID	RCT20
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	164
Reported Numeric Result	164
Reference Range low	128
Reference Range high	236
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.5
Reported Numeric Result	0.5
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	6.8
Reported Numeric Result	6.8
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	4.3
Reported Numeric Result	4.3
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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	RCT1407
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Lab Test Name	ALKALINE PHOSPHATASE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	68
Reported Numeric Result	68
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	120
Reported Numeric Result	120
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT15
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Lab Test Name	SERUM SODIUM
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	138
Reported Numeric Result	138
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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	RCT16
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Lab Test Name	SERUM POTASSIUM
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.1
Reported Numeric Result	0.1
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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Lab Test Name	GGT
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	19
Reported Numeric Result	19
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT392
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Lab Test Name	CREATININE (RATE BLANKED)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	1.0
Reported Numeric Result	1.0
Reference Range low	0.5
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition _____


Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

Lab Test Name ALT (SGPT)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	21
Reported Numeric Result	21
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition


Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

Lab Test Name UREA NITROGEN

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	14
Reported Numeric Result	14
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT10

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.39
Reported Numeric Result	0.39
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT100

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	30
Reported Numeric Result	30
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19


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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT102

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT11

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT12

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.01
Reported Numeric Result	0.01
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT13
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	233
Reported Numeric Result	233
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	56.2
Reported Numeric Result	56.2
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	36.1
Reported Numeric Result	36.1
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	5.7
Reported Numeric Result	5.7
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT18
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input 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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT19
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.1
Reported Numeric Result	0.1
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.4
Reported Numeric Result	5.4
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	92
Reported Numeric Result	92
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT40

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	16.3
Reported Numeric Result	16.3
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT7
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.90
Reported Numeric Result	6.90
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT71
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT8

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	3.88
Reported Numeric Result	3.88
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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	HMT9
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.49
Reported Numeric Result	2.49
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	1.028
Reported Numeric Result	1.028
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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	6.0
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Reported Numeric Result	6.0
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Reference Range low	5.0
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Reference Range high	8.0
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W616383
--------------	---------

Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
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Lab Test Name	UR PROTEIN
---------------	------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Test ID _____

Test Status Done 

Reported Text Result TRACE

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W616383

Actual Collection Date 2014 02 27

Actual Collection Time 05:44

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

Lab Test Name UR GLUCOSE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W616383
--------------	---------

Actual Collection Date	2014 02 27
------------------------	------------

Actual Collection Time	05:44
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
-------------	------

Lab Test Name	UR BILIRUBIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 14:51:30
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (1)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
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Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCRL
--------------	---------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	9.46
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (2)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
-------------------------	------------

Analyte	24(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	24RHCRL
--------------	---------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	6.56
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (3)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
-------------------------	------------

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: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (4)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
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Analyte	27-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	27HCRL
--------------	--------

Result	
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Result Unit	NG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	11.60
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (5)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
-------------------------	------------

Analyte	4B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	4BHCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	10.66
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (6)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
-------------------------	------------

Analyte	5A,6A-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5A6AECNL
--------------	----------

Result	
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Result Unit	NG/ML
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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	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (7)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
-------------------------	------------

Analyte	5B,6B-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5B6BECNL
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	26.83
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (8)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
-------------------------	------------

Analyte	6A-HYDROXY-5A-CHOLESTAN OL
---------	-------------------------------

Analyte code	6AH5ACNL
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Result	_____
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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	_____
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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: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (9)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
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Analyte	7-KETOCHOLESTEROL
---------	-------------------

Analyte code	7KCRL
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Result	
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Result Unit	NG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
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Lower limit of quantification	15.43
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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: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (10)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
-------------------------	------------

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: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (11)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
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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	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Oxysterol results (12)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3261638339
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Analyte	CHOLESTEROL
---------	-------------

Analyte code	CHOL
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Result	
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Result Unit	MG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
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Lower limit of quantification	0.50
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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: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_COHB (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003538
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	3.90
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-27
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:42

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Lab_BU_COHB (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003539
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	5.80
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-27
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:42

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment

2014 FEB 27
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

21:32
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

A lot ☒

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

Moderately ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

Moderately ☒

6. Did smoking make you feel less irritable?

Moderately ☒

7. Did smoking help you concentrate?

Moderately ☒

8. Did smoking reduce your hunger for food?

Moderately ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

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? Moderately ☐

12. Did you enjoy smoking? A lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

Reason not done	<hr/>
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Date of assessment	27 FEB 2014 DD/MMM/YYYY
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Time of assessment	21:03 hour:min 24-hour clock
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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.	Neither agree nor disagree <input type="radio"/>
--	--

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Neither agree nor disagree <input type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Disagree <input type="radio"/>
--	--------------------------------

If you agree or strongly agree, please describe :	<hr/>
---	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

4. The device is easy to use. Agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device. Disagree ☐

If you agree or strongly agree, please describe : _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Questionnaire on smoking urges (QSU)
Data signed: (jeanellek1) 18 Jun 2015 14:51:29
Generated On: 20 Jul 2016 01:42:19

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 FEB 27
DD/MMM/YYYY	
Time of assessment	21:31
hour:min 24-hour clock	
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Do not agree or disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Somewhat disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Somewhat disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Somewhat disagree <input type="radio"/>
5. All I want right now is a cigarette	Do not agree or 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	Somewhat agree <input type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	
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Battery ID	CG267
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Battery Name	FIBRINOGEN
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Lab Test ID	CGT285
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Lab Test Name	FIBRINOGEN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	350
Reported Numeric Result	350
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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
----------------------	------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W616383
--------------	---------

Actual Collection Date	2014 02 27
------------------------	------------

Actual Collection Time	05:44
------------------------	-------

Specimen Condition	
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Battery ID	CN236
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Battery Name	HOMOCYSTEINE
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Lab Test ID	CNT145
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Lab Test Name	HOMOCYSTEINE, EDTAPL
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	9.41
Reported Numeric Result	9.41
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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	
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Battery ID	IM2293
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Battery Name	SICAM-1
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Lab Test ID	IMT1768
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Lab Test Name	SICAM-1-RUO
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	264.4
Reported Numeric Result	264.4
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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	
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Battery ID	HM1054
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Battery Name	HEMOGLOBIN A1C
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Lab Test ID	HMT370
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	HEMOGLOBIN A1C,VARIANT(-70)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.2
Reported Numeric Result	5.2
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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
----------------------	------

Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	
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Battery ID	RC6871
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Battery Name	HDL
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Lab Test ID	RCT1684
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	51
Reported Numeric Result	51
Reference Range low	30
Reference Range high	63
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
------------------------	------------

Actual Collection Time	05:44
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Specimen Condition	
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Battery ID	SC3249
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Battery Name	HS-CRP
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Lab Test ID	SCT1528
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	C-REACTIVE PROTEIN (N HS)-QT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.172
Reported Numeric Result	0.172
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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	
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Battery ID	SC3582
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Battery Name	APOLIPOPROTEIN
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Lab Test ID	SCT3639
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Lab Test Name	APOLIPOPROTEIN A1, RAND
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	139
Reported Numeric Result	139
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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	
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Battery ID	SC3582
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Battery Name	APOLIPOPROTEIN
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Lab Test ID	SCT3643
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Lab Test Name	APOLIPOPROTEIN B, RAND
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	69
Reported Numeric Result	69
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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W616383
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Actual Collection Date	2014 02 27
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Actual Collection Time	05:44
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Specimen Condition	
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Battery ID	RC9267
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Battery Name	LDL
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Lab Test ID	RCT2394
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Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	91
Reported Numeric Result	91
Reference Range low	66
Reference Range high	147
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: 2146
Folder: Baseline (Day 0)
Form: Risk Markers(CCLS) (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:40
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003717
Analyte	HPMA
Sample type	URINE
Result	1270
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003717
Analyte	CEMA
Sample type	URINE
Result	149
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003717
Analyte	HBMA
Sample type	URINE
Result	352
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (NNN, NNAL)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004480
Analyte	NNAL
Sample type	URINE
Result	419
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004480
Analyte	NNN
Sample type	URINE
Result	21.7
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (HEMA)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (HEMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112470002236
Analyte	HEMA
Sample type	URINE
Result	4.32
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-05
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (HEMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

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

(1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:43

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000817
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Analyte	COT
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Sample type	URINE
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Result	1530
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-06
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Date of Collection	2014-FEB-27
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Timepoint-minutes	
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Urine Start Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:43

Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000817
Analyte	COT-GLUC
Sample type	URINE
Result	12500
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:43

Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000817
Analyte	NIC
Sample type	URINE
Result	1000
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:43

Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000817
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Analyte	NIC-GLUC
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Sample type	URINE
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Result	1550
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-06
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Date of Collection	2014-FEB-27
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Timepoint-minutes	
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Urine Start Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:43

Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000817
Analyte	THCOT
Sample type	URINE
Result	6610
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:43

Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000817
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Analyte	THCOT-GLUC
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Sample type	URINE
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Result	3010
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-06
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Date of Collection	2014-FEB-27
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Timepoint-minutes	
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Urine Start Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Baseline (Day 0)

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:43

Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (3-OH BaP)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112490002236
Analyte	3-OH BAP
Sample type	URINE
Result	89.7
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-07
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Caffeine, Paraxanthine)
Generated On: 20 Jul 2016 01:42:19

Sample type	PLASMA
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112500000640
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	435
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	0
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Celerion Study Number	AA99128-08
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Date of Collection	2014-FEB-27
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Timepoint-minutes	0
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)
Generated On: 20 Jul 2016 01:42:19

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112500000640
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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Result	959
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	0
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Celerion Study Number	AA99128-08
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Date of Collection	2014-FEB-27
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Timepoint-minutes	0
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)
Generated On: 20 Jul 2016 01:42:19

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002258
Analyte	1-NA
Sample type	URINE
Result	119
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002258
Analyte	2-NA
Sample type	URINE
Result	38.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002258
Analyte	4-ABP
Sample type	URINE
Result	24.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002258
Analyte	O-TOL
Sample type	URINE
Result	217
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (11-dTXb2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112530001634
Analyte	11-DTXB2
Sample type	URINE
Result	684
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-11
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (iPF2a-III)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112540001704
Analyte	IPF2A-III
Sample type	URINE
Result	687
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-12
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Ames)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Ames) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05113320000331
Analyte	AMES
Sample type	URINE
Result	5.09
Result Unit	REV/ML
Lab Status	OK
Sample comment	
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-15
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Ames) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (1-OHP)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115190004150
Analyte	1-OHP
Sample type	URINE
Result	189
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-03
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (SPMA, SBMA)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004141
Analyte	SBMA
Sample type	URINE
Result	5.54
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004141
Analyte	SPMA
Sample type	URINE
Result	3.57
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (MHBMA)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115180004150
Analyte	MHBMA
Sample type	URINE
Result	3.07
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-02
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:42
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Creatinine)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample type	URINE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115160002214
Analyte	CREATININE
Sample type	URINE
Result	201
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-14
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample type	PLASMA
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001046
Analyte	COT
Sample type	PLASMA
Result	208
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-01
Date of Collection	2014-FEB-27
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001046
Analyte	NIC
Sample type	PLASMA
Result	17.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-01
Date of Collection	2014-FEB-27
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112520000688
Analyte	COT
Sample type	PLASMA
Result	200
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-10
Date of Collection	2014-FEB-27
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112520000688
Analyte	THCOT
Sample type	PLASMA
Result	80.6
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-10
Date of Collection	2014-FEB-27
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Baseline (Day 0)
Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:43
Generated On: 20 Jul 2016 01:42:19

Urine End Day	0
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:51:44

Generated On: 20 Jul 2016 01:42:19

Date of Visit

28 FEB 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Vital Signs

Data signed: (jeanellek1) 18 Jun 2015 14:51:44

Generated On: 20 Jul 2016 01:42:19

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

10:14
hour:min 24-hour clock

Pulse rate

64
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

111
mmHg

Blood Pressure (diastolic)

63
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Plasma Nicotine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

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

Date DD/MMM/YYYY	28 FEB 2014
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Time hour:min 24-hour clock	20:56
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (jeanellek1) 18 Jun 2015 14:51:44

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
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Time hour:min 24-hour clock	20:56
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (jeanellek1) 18 Jun 2015 14:51:44

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:56
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: CO Breath Test (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:44

Generated On: 20 Jul 2016 01:42:19

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	06:35
---	-------

Result(ppm)	7
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: CO Breath Test (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

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	12:30
---	-------

Result(ppm)	5
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: CO Breath Test (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

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	16:10
---	-------

Result(ppm)	2
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: CO Breath Test (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

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	20:08
---	-------

Result(ppm)	5
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: 24 hour urine collections
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

Start Time	06:28
	hour:min 24-hour clock

End Date	01 MAR 2014
	DD/MMM/YYYY

End Time	06:45
	hour:min 24-hour clock

Volume	1096
	mL

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Sample Urine Collection
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

Were samples for 24h collected? Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected? 13

How many back up tubes were collected? 13

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 28
DD/MMM/YYYY

Time of assessment

06:06
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Mild ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Mild ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Mild ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☒

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

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? None ☒

10. Constipation

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

11. Dizziness

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

12. Coughing

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

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

13. Dreaming or nightmares

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

14. Nausea

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

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Cough Assessment
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 28
DD/MMM/YYYY

Time of assessment

06:05
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Lab_BU_COHB (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003540
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.50
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	1
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-28
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of assessment	2014 FEB 28
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	20:12
	hour:min 24-hour clock

Assessment Status	Completed
-------------------	-----------

1. Was smoking satisfying?	Moderately
----------------------------	------------

2. Did cigarettes taste good?	A lot
-------------------------------	-------

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

4. Did smoking calm you down?	Moderately
-------------------------------	------------

5. Did smoking make you feel more awake?	Moderately
--	------------

6. Did smoking make you feel less irritable?	Moderately
--	------------

7. Did smoking help you concentrate?	Moderately
--------------------------------------	------------

8. Did smoking reduce your hunger for food?	Little
---	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (jeanellek1) 18 Jun 2015 14:51:44

Generated On: 20 Jul 2016 01:42:19

9. Did smoking make you dizzy? Not at all ☐

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

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

12. Did you enjoy smoking? A lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Questionnaire on smoking urges (QSU)
Data signed: (jeanellek1) 18 Jun 2015 14:51:44
Generated On: 20 Jul 2016 01:42:19

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 FEB 28
DD/MMM/YYYY	
Time of assessment	20:11
hour:min 24-hour clock	
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Do not agree or disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Somewhat disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Do not agree or disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Somewhat disagree <input type="radio"/>
5. All I want right now is a cigarette	Somewhat disagree <input type="radio"/>
6. I have an urge for a cigarette	Somewhat disagree <input type="radio"/>
7. A cigarette would taste good now	Somewhat agree <input type="radio"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (jeanellek1) 18 Jun 2015 14:51:44

Generated On: 20 Jul 2016 01:42:19

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

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Do not agree or disagree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003718
Analyte	HPMA
Sample type	URINE
Result	729
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003718
Analyte	CEMA
Sample type	URINE
Result	62.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003718
Analyte	HBMA
Sample type	URINE
Result	204
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004481
Analyte	NNAL
Sample type	URINE
Result	228
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004481
Analyte	NNN
Sample type	URINE
Result	2.53
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (HEMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (HEMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112470002237
Analyte	HEMA
Sample type	URINE
Result	3.11
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-05
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

(1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000818
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Analyte	COT
---------	-----

Sample type	URINE
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Result	1100
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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	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	1
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day	2
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

(2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000818
----------------	----------------

Analyte	COT-GLUC
---------	----------

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

Result	9500
--------	------

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	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

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

Urine Start Day	1
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day	2
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000818
----------------	----------------

Analyte	NIC
---------	-----

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

Result	336
--------	-----

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	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

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

Urine Start Day	1
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day	2
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

(4)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000818
----------------	----------------

Analyte	NIC-GLUC
---------	----------

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

Result	976
--------	-----

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	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

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

Urine Start Day	1
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day	2
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

(5)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000818
----------------	----------------

Analyte	THCOT
---------	-------

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

Result	5440
--------	------

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	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

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

Urine Start Day	1
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day	2
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

(6)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000818
----------------	----------------

Analyte	THCOT-GLUC
---------	------------

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

Result	2340
--------	------

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	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

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

Urine Start Day	1
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day	2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112490002237
Analyte	3-OH BAP
Sample type	URINE
Result	47.0
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-07
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002259
Analyte	1-NA
Sample type	URINE
Result	22.4
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002259
Analyte	2-NA
Sample type	URINE
Result	8.93
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002259
Analyte	4-ABP
Sample type	URINE
Result	11.4
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002259
Analyte	O-TOL
Sample type	URINE
Result	103
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (1-OHP)

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115190004151
Analyte	1-OHP
Sample type	URINE
Result	141
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-03
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004142
Analyte	SBMA
Sample type	URINE
Result	3.88
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004142
Analyte	SPMA
Sample type	URINE
Result	1.69
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (MHBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115180004151
Analyte	MHBMA
Sample type	URINE
Result	0.563
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-02
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (Creatinine)

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115160002215
Analyte	CREATININE
Sample type	URINE
Result	187
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Sample type

PLASMA

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001047
Analyte	COT
Sample type	PLASMA
Result	154
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	AA99128-01
Date of Collection	2014-FEB-28
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 1
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:45
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001047
Analyte	NIC
Sample type	PLASMA
Result	9.88
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	AA99128-01
Date of Collection	2014-FEB-28
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:45

Generated On: 20 Jul 2016 01:42:19

Urine End Day

1

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Date of Visit

01 MAR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Vital Signs

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

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 11:22
hour:min 24-hour clock

Pulse rate 79
beats per minute

Respiratory rate 18
breaths per minute

Blood Pressure (systolic) 120
mmHg

Blood Pressure (diastolic) 67
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Plasma Nicotine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:29
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Plasma Cotinine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:29
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: CoHb Blood Sample
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:29
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: CO Breath Test (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

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	06:30
---	-------

Result(ppm)	3
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: CO Breath Test (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

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	12:13
---	-------

Result(ppm)	0
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: CO Breath Test (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

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	16:18
---	-------

Result(ppm)	3
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: CO Breath Test (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

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	20:11
---	-------

Result(ppm)	3
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: 24 hour urine collections
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Start Time	06:45
	hour:min 24-hour clock

End Date	02 MAR 2014
	DD/MMM/YYYY

End Time	06:28
	hour:min 24-hour clock

Volume	872
	mL

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Sample Urine Collection
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Were samples for 24h collected? Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected? 11

How many back up tubes were collected? 11

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 01
DD/MMM/YYYY

Time of assessment

06:46
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☐

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

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

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? None ☐

7. Insomnia, sleep problems, awakening at night

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

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? None ☐

10. Constipation

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

11. Dizziness

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

12. Coughing

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

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

13. Dreaming or nightmares

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

14. Nausea

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

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Cough Assessment
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 01
DD/MMM/YYYY

Time of assessment

06:45
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Lab_BU_COHB (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003541
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.20
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	2
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-01
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of assessment	2014 MAR 01
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	20:05
	hour:min 24-hour clock

Assessment Status	Completed
-------------------	-----------

1. Was smoking satisfying?	A lot
----------------------------	-------

2. Did cigarettes taste good?	A lot
-------------------------------	-------

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

4. Did smoking calm you down?	Moderately
-------------------------------	------------

5. Did smoking make you feel more awake?	Moderately
--	------------

6. Did smoking make you feel less irritable?	Moderately
--	------------

7. Did smoking help you concentrate?	Moderately
--------------------------------------	------------

8. Did smoking reduce your hunger for food?	Little
---	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

9. Did smoking make you dizzy? Not at all ☐

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

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

12. Did you enjoy smoking? Quite a lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Questionnaire on smoking urges (QSU)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 MAR 01
DD/MMM/YYYY	
Time of assessment	20:05
hour:min 24-hour clock	
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Do not agree or disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Somewhat disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Do not agree or disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Do not agree or disagree <input type="radio"/>
5. All I want right now is a cigarette	Do not agree or 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: 2146

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003719
Analyte	HPMA
Sample type	URINE
Result	793
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003719
Analyte	CEMA
Sample type	URINE
Result	46.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003719
Analyte	HBMA
Sample type	URINE
Result	154
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004482
Analyte	NNAL
Sample type	URINE
Result	230
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004482
Analyte	NNN
Sample type	URINE
Result	1.96
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Urine End Day	3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (HEMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (HEMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:46
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112470002238
Analyte	HEMA
Sample type	URINE
Result	2.01
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:46

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

(1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000819
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Analyte	COT
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Sample type	URINE
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Result	1550
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-02
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Timepoint-minutes	
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Urine Start Day	2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day	3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

(2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000819
Analyte	COT-GLUC
Sample type	URINE
Result	13100
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day	3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000819
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Analyte	NIC
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Sample type	URINE
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Result	2120
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-02
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Timepoint-minutes	
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Urine Start Day	2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

(4)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000819
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Analyte	NIC-GLUC
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Sample type	URINE
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Result	2280
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-02
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day	3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

(5)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000819
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Analyte	THCOT
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Sample type	URINE
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Result	7060
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-02
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Timepoint-minutes	
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Urine Start Day	2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day	3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

(6)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000819
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Analyte	THCOT-GLUC
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Sample type	URINE
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Result	3590
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-02
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Timepoint-minutes	
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Urine Start Day	2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day	3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112490002238
Analyte	3-OH BAP
Sample type	URINE
Result	58.1
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-07
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002260
Analyte	1-NA
Sample type	URINE
Result	15.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002260
Analyte	2-NA
Sample type	URINE
Result	7.82
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002260
Analyte	4-ABP
Sample type	URINE
Result	4.47
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002260
Analyte	O-TOL
Sample type	URINE
Result	117
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (1-OHP)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115190004152
Analyte	1-OHP
Sample type	URINE
Result	204
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004143
Analyte	SBMA
Sample type	URINE
Result	11.1
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004143
Analyte	SPMA
Sample type	URINE
Result	1.08
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (MHBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115180004152
Analyte	MHBMA
Sample type	URINE
Result	0.333
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (Creatinine)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115160002216
Analyte	CREATININE
Sample type	URINE
Result	254
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Sample type

PLASMA

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001048
Analyte	COT
Sample type	PLASMA
Result	209
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-01
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 2
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001048
Analyte	NIC
Sample type	PLASMA
Result	22.3
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-01
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:47

Generated On: 20 Jul 2016 01:42:19

Urine End Day

2

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Date of Visit

02 MAR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Vital Signs

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Time of assessment

10:56
hour:min 24-hour clock

Pulse rate

80
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

114
mmHg

Blood Pressure (diastolic)

71
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Plasma Nicotine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:15
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Plasma Cotinine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:15
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: CoHb Blood Sample
Data signed: (jeanellek1) 18 Jun 2015 14:51:47
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:15
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: CO Breath Test (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

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	06:31
---	-------

Result(ppm)	2
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: CO Breath Test (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

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	12:12
---	-------

Result(ppm)	03
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: CO Breath Test (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

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	16:21
---	-------

Result(ppm)	01
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: CO Breath Test (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

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	20:26
---	-------

Result(ppm)	2
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: 24 hour urine collections

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Start Time	06:28
	hour:min 24-hour clock

End Date	03 MAR 2014
	DD/MMM/YYYY

End Time	06:28
	hour:min 24-hour clock

Volume	1036
	mL

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Sample Urine Collection
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Were samples for 24h collected? Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected? 11

How many back up tubes were collected? 11

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 02
DD/MMM/YYYY

Time of assessment

06:01
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Slight ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☐

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

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

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? None ☐

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

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

13. Dreaming or nightmares

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

14. Nausea

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

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Cough Assessment
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 02
DD/MMM/YYYY

Time of assessment

06:01
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Lab_BU_COHB (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003542
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.20
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	3
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-02
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 02 DD/MMM/YYYY
Time of assessment	21:29 hour:min 24-hour clock
Assessment Status	Completed
1. Was smoking satisfying?	Moderately
2. Did cigarettes taste good?	Moderately
3. Did you enjoy the sensation in your throat and chest?	Moderately
4. Did smoking calm you down?	Moderately
5. Did smoking make you feel more awake?	Moderately
6. Did smoking make you feel less irritable?	Moderately
7. Did smoking help you concentrate?	Moderately
8. Did smoking reduce your hunger for food?	Moderately

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

9. Did smoking make you dizzy? Not at all ☐

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

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

12. Did you enjoy smoking? A lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Questionnaire on smoking urges (QSU)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 MAR 02
DD/MMM/YYYY	
Time of assessment	21:27
hour:min 24-hour clock	
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Do not agree or disagree <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	Do not agree or disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Do not agree or disagree <input type="radio"/>
5. All I want right now is a cigarette	Do not agree or 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: 2146

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

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

10. I am going to smoke as soon as possible Do not agree or disagree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003720
Analyte	HPMA
Sample type	URINE
Result	1020
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003720
Analyte	CEMA
Sample type	URINE
Result	44.0
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003720
Analyte	HBMA
Sample type	URINE
Result	188
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004483
Analyte	NNAL
Sample type	URINE
Result	239
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004483
Analyte	NNN
Sample type	URINE
Result	2.63
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (HEMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (HEMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112470002239
Analyte	HEMA
Sample type	URINE
Result	2.15
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

(1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000820
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Analyte	COT
---------	-----

Sample type	URINE
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Result	2380
--------	------

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

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-03
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	3
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day	4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000820
----------------	----------------

Analyte	COT-GLUC
---------	----------

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

Result	19800
--------	-------

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

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-03
--------------------	-------------

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

Urine Start Day	3
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000820
----------------	----------------

Analyte	NIC
---------	-----

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

Result	3540
--------	------

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

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-03
--------------------	-------------

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

Urine Start Day	3
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

(4)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000820
----------------	----------------

Analyte	NIC-GLUC
---------	----------

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

Result	3080
--------	------

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

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-03
--------------------	-------------

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

Urine Start Day	3
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

(5)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000820
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Analyte	THCOT
---------	-------

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

Result	11300
--------	-------

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

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-03
--------------------	-------------

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

Urine Start Day	3
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

(6)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000820
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Analyte	THCOT-GLUC
---------	------------

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

Result	4600
--------	------

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

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-03
--------------------	-------------

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

Urine Start Day	3
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (3-OH BaP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112490002239
----------------	----------------

Analyte	3-OH BAP
---------	----------

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

Result	BLQ<(25.0)
--------	------------

Result Unit	FG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-MAR-02
--------------------	-------------

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

Urine Start Day	3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002261
Analyte	1-NA
Sample type	URINE
Result	14.7
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002261
Analyte	2-NA
Sample type	URINE
Result	9.37
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002261
Analyte	4-ABP
Sample type	URINE
Result	4.80
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002261
Analyte	O-TOL
Sample type	URINE
Result	183
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (1-OHP)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115190004153
Analyte	1-OHP
Sample type	URINE
Result	253
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004144
Analyte	SBMA
Sample type	URINE
Result	11.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004144
Analyte	SPMA
Sample type	URINE
Result	0.909
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (MHBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115180004153
Analyte	MHBMA
Sample type	URINE
Result	0.389
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (Creatinine)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115160002217
Analyte	CREATININE
Sample type	URINE
Result	293
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Sample type

PLASMA

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001049
Analyte	COT
Sample type	PLASMA
Result	257
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-02
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 3
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:48
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001049
Analyte	NIC
Sample type	PLASMA
Result	17.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-02
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:48

Generated On: 20 Jul 2016 01:42:19

Urine End Day

3

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Date of Visit

03 MAR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Vital Signs

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 10:15
hour:min 24-hour clock

Pulse rate 82
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 108
mmHg

Blood Pressure (diastolic) 63
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Socio-Economic Status
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date 03 MAR 2014
DD/MMM/YYYY

Time 05:55
hour:min 24-hour clock

Q1. What is the highest level of education you have completed? Some College ☒

Q2. What is your current occupational status? Working now ☒

SPECIFY _____

Q3. How many people are currently living in your household, including yourself? 02

Q4. Of these people, how many are children? 00

Q5. Of these people, how many are adults? 02

Q6. Of the adults, how many bring income into the household? 02

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Socio-Economic Status

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Q7. Which of these categories best describes your total combined family income for the past 12 months? This should include income (before taxes) from all sources, wages, rent from properties, social security, disability and/or veteran's benefits, unemployment benefits, workman's compensation, help from relatives (including child payments and alimony), and so on.

\$45,000 through \$59,999 ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Plasma Nicotine Sample

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:41
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Plasma Cotinine Sample

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:41
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: CoHb Blood Sample

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:41
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: CO Breath Test (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

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	06:34
---	-------

Result(ppm)	1
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: CO Breath Test (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:24
---	-------

Result(ppm)	1
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: CO Breath Test (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

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	16:14
---	-------

Result(ppm)	2
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: CO Breath Test (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

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	20:12
---	-------

Result(ppm)	4
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: 24 hour urine collections

Data signed: (jeanellek1) 18 Jun 2015 14:51:49

Generated On: 20 Jul 2016 01:42:19

Start Time	06:30
	hour:min 24-hour clock

End Date	04 MAR 2014
	DD/MMM/YYYY

End Time	06:34
	hour:min 24-hour clock

Volume	1633
	mL

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Sample Urine Collection
Data signed: (jeanellek1) 18 Jun 2015 14:51:49
Generated On: 20 Jul 2016 01:42:19

Were samples for 24h collected? Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected? 11

How many back up tubes were collected? 11

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 03
DD/MMM/YYYY

Time of assessment

06:01
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Slight ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Mild ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Slight ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Slight ☒

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

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

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? None ☐

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

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

13. Dreaming or nightmares

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

14. Nausea

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

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Cough Assessment
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 03
DD/MMM/YYYY

Time of assessment

06:00
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Lab_BU_COHB (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003543
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.80
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	4
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-03
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:50

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 03 DD/MMM/YYYY
Time of assessment	20:49 hour:min 24-hour clock
Assessment Status	Completed
1. Was smoking satisfying?	Moderately
2. Did cigarettes taste good?	Moderately
3. Did you enjoy the sensation in your throat and chest?	Moderately
4. Did smoking calm you down?	Moderately
5. Did smoking make you feel more awake?	Moderately
6. Did smoking make you feel less irritable?	Moderately
7. Did smoking help you concentrate?	Moderately
8. Did smoking reduce your hunger for food?	Moderately

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

9. Did smoking make you dizzy? Not at all ☐

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

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

12. Did you enjoy smoking? Moderately ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
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Reason not done	<hr/>
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Date of assessment	03 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:34 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input checked="" type="radio"/>
--	---

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Neither agree nor disagree <input checked="" type="radio"/>
---	---

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input checked="" type="radio"/>
--	---

If you agree or strongly agree, please describe :	<hr/>
---	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

4. The device is easy to use. Neither agree nor disagree ☐

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device. Neither agree nor disagree ☐

If you agree or strongly agree, please describe : _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Questionnaire on smoking urges (QSU)
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 MAR 03
DD/MMM/YYYY	
Time of assessment	20:49
hour:min 24-hour clock	
Assessment Status	Completed <input type="checkbox"/>
1. I have a desire for a cigarette right now	Do not agree or disagree <input type="checkbox"/>
2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input type="checkbox"/>
3. If it were possible I would probably smoke now	Do not agree or disagree <input type="checkbox"/>
4. I could control things better right now if I could smoke	Do not agree or disagree <input type="checkbox"/>
5. All I want right now is a cigarette	Do not agree or disagree <input type="checkbox"/>
6. I have an urge for a cigarette	Do not agree or disagree <input type="checkbox"/>
7. A cigarette would taste good now	Do not agree or disagree <input type="checkbox"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (jeanellek1) 18 Jun 2015 14:51:50

Generated On: 20 Jul 2016 01:42:19

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

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

10. I am going to smoke as soon as possible Do not agree or disagree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003721
Analyte	HPMA
Sample type	URINE
Result	300
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003721
Analyte	CEMA
Sample type	URINE
Result	9.98
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003721
Analyte	HBMA
Sample type	URINE
Result	47.1
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (jeanellek1) 18 Jun 2015 14:51:50

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004484
Analyte	NNAL
Sample type	URINE
Result	88.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:50

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004484
Analyte	NNN
Sample type	URINE
Result	1.37
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:50

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (HEMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:50

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (HEMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:50
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112470002240
Analyte	HEMA
Sample type	URINE
Result	0.384
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:50

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

(1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000821
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Analyte	COT
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Sample type	URINE
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Result	1430
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	4
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-04
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Timepoint-minutes	
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Urine Start Day	4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

(2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000821
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Analyte	COT-GLUC
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Sample type	URINE
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Result	8030
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-04
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Timepoint-minutes	
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Urine Start Day	4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000821
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Analyte	NIC
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Sample type	URINE
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Result	1460
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-04
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Timepoint-minutes	
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Urine Start Day	4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day	5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000821
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Analyte	NIC-GLUC
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Sample type	URINE
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Result	986
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-04
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

(5)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000821
Analyte	THCOT
Sample type	URINE
Result	6080
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

(6)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000821
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Analyte	THCOT-GLUC
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Sample type	URINE
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Result	2350
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Result Unit	NG/ML
-------------	-------

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

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

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAR-04
--------------------	-------------

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

Urine Start Day	4
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day	5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112490002240
Analyte	3-OH BAP
Sample type	URINE
Result	BLQ<(25.0)
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-07
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002262
Analyte	1-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002262
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002262
Analyte	4-ABP
Sample type	URINE
Result	BLQ<(1.50)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002262
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (1-OHP)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115190004154
Analyte	1-OHP
Sample type	URINE
Result	73.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004145
Analyte	SBMA
Sample type	URINE
Result	3.41
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

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

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004145
Analyte	SPMA
Sample type	URINE
Result	0.192
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (MHBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115180004154
Analyte	MHBMA
Sample type	URINE
Result	BLQ<(0.100)
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (Creatinine)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115160002218
Analyte	CREATININE
Sample type	URINE
Result	95.1
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Sample type

PLASMA

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001050
Analyte	COT
Sample type	PLASMA
Result	268
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-03
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 4
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001050
Analyte	NIC
Sample type	PLASMA
Result	16.7
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-03
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Urine End Day

4

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:51:59

Generated On: 20 Jul 2016 01:42:19

Date of Visit

04 MAR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Vital Signs

Data signed: (jeanellek1) 18 Jun 2015 14:51:59

Generated On: 20 Jul 2016 01:42:19

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

10:14
hour:min 24-hour clock

Pulse rate

72
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

108
mmHg

Blood Pressure (diastolic)

62
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Plasma Nicotine Samples <Day 5> (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:02
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:50
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Plasma Nicotine Samples <Day 5> (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:02
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:51
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Plasma Nicotine Samples <Day 5> (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:02
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:45
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Plasma Nicotine Samples <Day 5> (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:02
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	12:46
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Plasma Nicotine Samples <Day 5> (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:02
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:44
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (6)

Data signed: (jeanellek1) 18 Jun 2015 14:52:02

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:46
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Plasma Nicotine Samples <Day 5> (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:02
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:44
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (8)

Data signed: (jeanellek1) 18 Jun 2015 14:52:02

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	20:48
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (9)

Data signed: (jeanellek1) 18 Jun 2015 14:52:02

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:43
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:01

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:50
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Plasma Cotinine Samples <Day 5> (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:01
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:51
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Plasma Cotinine Samples <Day 5> (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:01
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:45
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Plasma Cotinine Samples <Day 5> (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:01
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	12:46
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (5)

Data signed: (jeanellek1) 18 Jun 2015 14:52:01

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:44
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (6)

Data signed: (jeanellek1) 18 Jun 2015 14:52:01

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:46
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (7)

Data signed: (jeanellek1) 18 Jun 2015 14:52:01

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:44
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (8)

Data signed: (jeanellek1) 18 Jun 2015 14:52:01

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	20:48
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (9)

Data signed: (jeanellek1) 18 Jun 2015 14:52:01

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:43
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: CoHb Blood Sample(CC/THS) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:00
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:50
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:52:00

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	12:46
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:52:00

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	16:15
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (4)

Data signed: (jeanellek1) 18 Jun 2015 14:52:00

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:48
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: CO Breath Test (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:59
Generated On: 20 Jul 2016 01:42:19

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	06:21
---	-------

Result(ppm)	4
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: CO Breath Test (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:59

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:09
---	-------

Result(ppm)	0
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: CO Breath Test (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:59

Generated On: 20 Jul 2016 01:42:19

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	16:20
---	-------

Result(ppm)	0
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: CO Breath Test (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:59
Generated On: 20 Jul 2016 01:42:19

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	20:07
---	-------

Result(ppm)	3
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: CYP1A2 activity Sample

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Time of caffeine tablet intake	10:03
	hour:min 24-hour clock

Sample collection Not Done	False
----------------------------	-------

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
04 MAR 2014	16:15	Caffeine
04 MAR 2014	16:15	Paraxanthine

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: 24 hour urine collections

Data signed: (jeanellek1) 18 Jun 2015 14:51:58

Generated On: 20 Jul 2016 01:42:19

Start Time	06:34
	hour:min 24-hour clock

End Date	05 MAR 2014
	DD/MMM/YYYY

End Time	06:27
	hour:min 24-hour clock

Volume	1803
	mL

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Sample Urine Collection

Data signed: (jeanellek1) 18 Jun 2015 14:51:58

Generated On: 20 Jul 2016 01:42:19

Were samples for 24h collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

13

How many back up tubes were collected?

13

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:52:03
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 04
DD/MMM/YYYY

Time of assessment

06:05
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Mild ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Mild ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Mild ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☒

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:52:03
Generated On: 20 Jul 2016 01:42:19

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:52:03
Generated On: 20 Jul 2016 01:42:19

How have you been feeling over the past 24 hours?

Mild ☒

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: 2146
Folder: Day 5
Form: Cough Assessment
Data signed: (jeanellek1) 18 Jun 2015 14:52:04
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 04
DD/MMM/YYYY

Time of assessment

06:04
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Lab_BU_COHB (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:04
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003544
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	3.10
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-04
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:04

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Lab_BU_COHB (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:04
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003545
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.60
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	12
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-04
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (jeanellek1) 18 Jun 2015 14:52:04

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Lab_BU_COHB (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:04
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003546
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.50
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-04
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (jeanellek1) 18 Jun 2015 14:52:04

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Lab_BU_COHB (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:04
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003547
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.80
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-04
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (jeanellek1) 18 Jun 2015 14:52:04

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:52:03
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 04 DD/MMM/YYYY
Time of assessment	20:39 hour:min 24-hour clock
Assessment Status	Completed
1. Was smoking satisfying?	Moderately
2. Did cigarettes taste good?	Moderately
3. Did you enjoy the sensation in your throat and chest?	Moderately
4. Did smoking calm you down?	Moderately
5. Did smoking make you feel more awake?	Moderately
6. Did smoking make you feel less irritable?	Moderately
7. Did smoking help you concentrate?	Moderately
8. Did smoking reduce your hunger for food?	Moderately

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:52:03
Generated On: 20 Jul 2016 01:42:19

9. Did smoking make you dizzy? Not at all ☐

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

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

12. Did you enjoy smoking? A lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Behavioral Risk Factor Surveillance System Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:51:51
Generated On: 20 Jul 2016 01:42:19

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

Was paper questionnaire used?	Yes <input type="radio"/>
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Reason not done	<hr/>
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Date of assessment	04 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:34 hour:min 24-hour clock
--------------------	---------------------------------

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

Do you now smoke cigarettes every day, some days, or not at all?	Every day <input type="radio"/>
--	---------------------------------

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?	No <input type="radio"/>
--	--------------------------

How long has it been since you last smoked a cigarette, even one or two puffs?	<hr/>
--	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (jeanellek1) 18 Jun 2015 14:51:51

Generated On: 20 Jul 2016 01:42:19

Do you currently use chewing tobacco, snuff, or snus
every day, some days, or not at all?

Not at all ☐

NOTE: Snus (Swedish for snuff) is a moist smokeless
tobacco, usually sold in small pouches that are placed
under the lip against the gum.

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	04 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:35 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

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

Years	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL 100'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	04 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:35 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL 100'S

Time

Currently (last 3 months) ☒

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

Manufactured Cigarettes
per day

12

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: 2146

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:51:52

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	04 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:35 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL 100'S

Time _____

1 year ago ☒

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

Manufactured Cigarettes
per day

10

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: 2146

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:51:52

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	04 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:35 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL 100'S

Time _____

5 years ago ☒

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

Manufactured Cigarettes
per day

08

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: 2146

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:51:52

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	04 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:35 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL 100'S

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: 2146

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (jeanellek1) 18 Jun 2015 14:51:52

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	04 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:35 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL 100'S

Time _____ 15 years ago ☒

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

Manufactured Cigarettes
per day _____

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

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (jeanellek1) 18 Jun 2015 14:51:52

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	04 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:35 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL 100'S

Time _____ 20 years ago ☒

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

Manufactured Cigarettes
per day _____

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

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (jeanellek1) 18 Jun 2015 14:51:52

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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

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

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

Date of assessment	04 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:35 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Smoking Questionnaire (SQ) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:52
Generated On: 20 Jul 2016 01:42:19

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 _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? MARLBORO MENTHOL 100'S

Time _____ More than 20 years ago ☒

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

Manufactured Cigarettes
per day _____

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

Hand-rolled Cigarettes
per day _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (jeanellek1) 18 Jun 2015 14:51:52

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 5
Form: Supplemental Questions
Data signed: (jeanellek1) 18 Jun 2015 14:51:58
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 04 MAR 2014
DD/MMM/YYYY

Time of assessment 20:37

1. How long it takes for the subject to complete the SQ 01 minutes

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Supplemental Questions (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:58
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 04 MAR 2014
DD/MMM/YYYY

Time of assessment 20:37

1. How long it takes for the subject to complete the SQ 01 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: 2146
Folder: Day 5
Form: Supplemental Questions (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:58
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 04 MAR 2014
DD/MMM/YYYY

Time of assessment 20:37

1. How long it takes for the subject to complete the SQ 01 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: 2146
Folder: Day 5
Form: Supplemental Questions (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:58
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 04 MAR 2014
DD/MMM/YYYY

Time of assessment 20:37

1. How long it takes for the subject to complete the SQ 01 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: 2146
Folder: Day 5
Form: Supplemental Questions (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:58
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 04 MAR 2014
DD/MMM/YYYY

Time of assessment 20:37

1. How long it takes for the subject to complete the SQ 01 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: 2146
Folder: Day 5
Form: Supplemental Questions (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:58
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 04 MAR 2014
DD/MMM/YYYY

Time of assessment 20:37

1. How long it takes for the subject to complete the SQ 01 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Supplemental Questions (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:58
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 04 MAR 2014
DD/MMM/YYYY

Time of assessment 20:37

1. How long it takes for the subject to complete the SQ 01 minutes

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Questionnaire on smoking urges (QSU)
Data signed: (jeanellek1) 18 Jun 2015 14:52:04
Generated On: 20 Jul 2016 01:42:19

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 MAR 04
DD/MMM/YYYY	
Time of assessment	20:38
hour:min 24-hour clock	
Assessment Status	Completed <input type="checkbox"/>
1. I have a desire for a cigarette right now	Do not agree or disagree <input type="checkbox"/>
2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input type="checkbox"/>
3. If it were possible I would probably smoke now	Do not agree or disagree <input type="checkbox"/>
4. I could control things better right now if I could smoke	Do not agree or disagree <input type="checkbox"/>
5. All I want right now is a cigarette	Do not agree or disagree <input type="checkbox"/>
6. I have an urge for a cigarette	Do not agree or disagree <input type="checkbox"/>
7. A cigarette would taste good now	Do not agree or disagree <input type="checkbox"/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (jeanellek1) 18 Jun 2015 14:52:04

Generated On: 20 Jul 2016 01:42:19

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

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

10. I am going to smoke as soon as possible Do not agree or disagree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:52:07

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:07
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003722
Analyte	HPMA
Sample type	URINE
Result	468
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:07

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:07
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003722
Analyte	CEMA
Sample type	URINE
Result	15.9
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:52:07

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:07
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003722
Analyte	HBMA
Sample type	URINE
Result	76.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:52:07

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (jeanellek1) 18 Jun 2015 14:52:04

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:04
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004485
Analyte	NNAL
Sample type	URINE
Result	82.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:04

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:04
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004485
Analyte	NNN
Sample type	URINE
Result	1.55
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:52:04

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (HEMA)

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (HEMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:05
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112470002241
Analyte	HEMA
Sample type	URINE
Result	0.936
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

(1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000822
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Analyte	COT
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Sample type	URINE
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Result	1750
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-04
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

(2)

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000822
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Analyte	COT-GLUC
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Sample type	URINE
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Result	7390
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	5
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-04
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000822
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Analyte	NIC
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Sample type	URINE
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Result	560
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-04
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Timepoint-minutes	
-------------------	--

Urine Start Day	5
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

(4)

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000822
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Analyte	NIC-GLUC
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Sample type	URINE
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Result	996
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-04
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	5
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

(5)

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000822
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Analyte	THCOT
---------	-------

Sample type	URINE
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Result	4870
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-04
--------------------	-------------

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

Urine Start Day	5
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

(6)

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000822
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Analyte	THCOT-GLUC
---------	------------

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

Result	1790
--------	------

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

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

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

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-04
--------------------	-------------

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

Urine Start Day	5
-----------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:08

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP)

Data signed: (jeanellek1) 18 Jun 2015 14:52:09

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:09
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112490002241
Analyte	3-OH BAP
Sample type	URINE
Result	BLQ<(25.0)
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-07
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:09

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Caffeine, Paraxanthine)
Generated On: 20 Jul 2016 01:42:19

Sample type

PLASMA

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112500000641
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	985
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-MAR-04
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)
Generated On: 20 Jul 2016 01:42:19

Urine End Day	5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112500000641
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Analyte	PARAXANTHINE
---------	--------------

Sample type	PLASMA
-------------	--------

Result	1310
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Result Unit	NG/ML
-------------	-------

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

Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-MAR-04
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Timepoint-minutes	0
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Urine Start Day	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)
Generated On: 20 Jul 2016 01:42:19

Urine End Day	5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:09

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:09
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002263
Analyte	1-NA
Sample type	URINE
Result	2.63
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:09

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:09
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002263
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:09

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:09
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002263
Analyte	4-ABP
Sample type	URINE
Result	2.78
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:52:09

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:09
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002263
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:09

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2)

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:05
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112530001635
Analyte	11-DTXB2
Sample type	URINE
Result	324
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-11
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III)

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:05
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112540001705
Analyte	IPF2A-III
Sample type	URINE
Result	311
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-12
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (Ames)

Data signed: (jeanellek1) 18 Jun 2015 14:52:10

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (Ames) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:10
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05113320000332
Analyte	AMES
Sample type	URINE
Result	1.26
Result Unit	REV/ML
Lab Status	OK
Sample comment	
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-15
Date of Collection	2014-MAR-05
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:10

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (1-OHP)

Data signed: (jeanellek1) 18 Jun 2015 14:52:11

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:11
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115190004155
Analyte	1-OHP
Sample type	URINE
Result	47.9
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:11

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:05
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004146
Analyte	SBMA
Sample type	URINE
Result	3.10
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:05
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004146
Analyte	SPMA
Sample type	URINE
Result	0.168
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (MHBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:05
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115180004155
Analyte	MHBMA
Sample type	URINE
Result	0.118
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:05

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (Creatinine)

Data signed: (jeanellek1) 18 Jun 2015 14:52:11

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:11
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115160002219
Analyte	CREATININE
Sample type	URINE
Result	103
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:11

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Sample type

PLASMA

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001051
Analyte	COT
Sample type	PLASMA
Result	246
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	-15
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001051
Analyte	NIC
Sample type	PLASMA
Result	8.65
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	-15
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001052
Analyte	COT
Sample type	PLASMA
Result	262
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	2
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001052
Analyte	NIC
Sample type	PLASMA
Result	26.9
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	2
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001053
Analyte	COT
Sample type	PLASMA
Result	287
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	4
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001053
Analyte	NIC
Sample type	PLASMA
Result	18.3
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	4
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001054
Analyte	COT
Sample type	PLASMA
Result	297
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001054
Analyte	NIC
Sample type	PLASMA
Result	18.9
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001055
Analyte	COT
Sample type	PLASMA
Result	294
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	8
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001055
Analyte	NIC
Sample type	PLASMA
Result	15.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	8
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001056
Analyte	COT
Sample type	PLASMA
Result	302
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	10
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001056
Analyte	NIC
Sample type	PLASMA
Result	18.3
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	10
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001057
Analyte	COT
Sample type	PLASMA
Result	308
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	12
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001057
Analyte	NIC
Sample type	PLASMA
Result	15.1
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	12
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001058
Analyte	COT
Sample type	PLASMA
Result	326
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	14
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001058
Analyte	NIC
Sample type	PLASMA
Result	19.9
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	14
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001059
Analyte	COT
Sample type	PLASMA
Result	327
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 5
Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)
Data signed: (jeanellek1) 18 Jun 2015 14:52:06
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001059
Analyte	NIC
Sample type	PLASMA
Result	24.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (jeanellek1) 18 Jun 2015 14:52:06

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:52:13

Generated On: 20 Jul 2016 01:42:19

Date of Visit

05 MAR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:13

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T0 + 20H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	02:58
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (2)

Data signed: (jeanellek1) 18 Jun 2015 14:52:13

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Plasma Cotinine Samples <Day 6> (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:13
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T0 + 20H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	02:58
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Plasma Cotinine Samples <Day 6> (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:13
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:48
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: CoHb Blood Sample <prior to gas transfer and product>
Data signed: (jeanellek1) 18 Jun 2015 14:52:13
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Oxysterols

Data signed: (jeanellek1) 18 Jun 2015 14:52:12

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

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

Date DD/MMM/YYYY 05 MAR 2014

Time hour:min 24-hour clock 06:48

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: CYP2A6 activity Sample

Data signed: (jeanellek1) 18 Jun 2015 14:52:12

Generated On: 20 Jul 2016 01:42:19

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

05 MAR 2014

06:48

trans-3'-hydroxyc
otinine

05 MAR 2014

06:48

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Risk Marker: sICAM-1

Data signed: (jeanellek1) 18 Jun 2015 14:52:11

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:52:14
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 05
DD/MMM/YYYY

Time of assessment

06:36
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Mild ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Mild ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Mild ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☒

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:52:14
Generated On: 20 Jul 2016 01:42:19

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

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? Mild ☐

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Data signed: (jeanellek1) 18 Jun 2015 14:52:14
Generated On: 20 Jul 2016 01:42:19

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

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: 2146
Folder: Day 6
Form: Cough Assessment
Data signed: (jeanellek1) 18 Jun 2015 14:52:14
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 05
DD/MMM/YYYY

Time of assessment

06:35
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Bio-banking (Transcriptomics)

Data signed: (jeanellek1) 18 Jun 2015 14:52:14

Generated On: 20 Jul 2016 01:42:19

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:48
hour:min 24-hour clock

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

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (jeanellek1) 18 Jun 2015 14:52:14

Generated On: 20 Jul 2016 01:42:19

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

Yes ☒

Time of Sample Collection

06:48
hour:min 24-hour clock

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

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (jeanellek1) 18 Jun 2015 14:52:15

Generated On: 20 Jul 2016 01:42:19

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

Time of Buccal Collection 10:35
hour:min 24-hour clock

Time of Nasal Epithelial Collection 10:33
hour:min 24-hour clock

Was the subject fasting for at least 30 minutes at time of sample collection? Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Oxysterol results (1)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCR L
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Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	9.46
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Oxysterol results (2)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
-------------------------	------------

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	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Oxysterol results (3)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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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	
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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: 2146
Folder: Day 6
Form: Oxysterol results (4)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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Analyte	27-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	27HCRL
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Result	
--------	--

Result Unit	NG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	11.60
-------------------------------	-------

Date of Collection DD MMM YYYY	
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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: 2146
Folder: Day 6
Form: Oxysterol results (5)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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Analyte	4B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	4BHCRL
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Result	
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Result Unit	NG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
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Lower limit of quantification	10.66
-------------------------------	-------

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: 2146
Folder: Day 6
Form: Oxysterol results (6)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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Analyte	5A,6A-EPOXYCHOLESTANOL
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Analyte code	5A6AECNL
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Result	
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Result Unit	NG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
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Lower limit of quantification	12.46
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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: 2146
Folder: Day 6
Form: Oxysterol results (7)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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Analyte	5B,6B-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5B6BECNL
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Result	
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Result Unit	NG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
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Lower limit of quantification	26.83
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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: 2146
Folder: Day 6
Form: Oxysterol results (8)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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Analyte	6A-HYDROXY-5A-CHOLESTAN OL
---------	-------------------------------

Analyte code	6AH5ACNL
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Result	_____
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Result Unit	NG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
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Lower limit of quantification	13.70
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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: 2146
Folder: Day 6
Form: Oxysterol results (9)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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Analyte	7-KETOCHOLESTEROL
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Analyte code	7KCRL
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Result	
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Result Unit	NG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
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Lower limit of quantification	15.43
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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: 2146
Folder: Day 6
Form: Oxysterol results (10)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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Analyte	7A-HYDROXYCHOLESTEROL
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Analyte code	7AHCRL
--------------	--------

Result	
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Result Unit	NG/ML
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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	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Oxysterol results (11)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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Analyte	7B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7BHCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.86
-------------------------------	-------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Oxysterol results (12)
Generated On: 20 Jul 2016 01:42:19

Sample Accession number	3262621015
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Analyte	CHOLESTEROL
---------	-------------

Analyte code	CHOL
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Result	
--------	--

Result Unit	MG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	0.50
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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: 2146
Folder: Day 6
Form: Lab_BU_COHB (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:15
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003548
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.60
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	6
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-05
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:15

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:52:13
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 05 DD/MMM/YYYY
Time of assessment	06:37 hour:min 24-hour clock
Assessment Status	Completed
1. Was smoking satisfying?	Moderately
2. Did cigarettes taste good?	Moderately
3. Did you enjoy the sensation in your throat and chest?	Moderately
4. Did smoking calm you down?	Moderately
5. Did smoking make you feel more awake?	Moderately
6. Did smoking make you feel less irritable?	Moderately
7. Did smoking help you concentrate?	Moderately
8. Did smoking reduce your hunger for food?	Moderately

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Data signed: (jeanellek1) 18 Jun 2015 14:52:13
Generated On: 20 Jul 2016 01:42:19

9. Did smoking make you dizzy? Not at all ☐

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

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

12. Did you enjoy smoking? Quite a lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Questionnaire on smoking urges (QSU)
Data signed: (jeanellek1) 18 Jun 2015 14:52:14
Generated On: 20 Jul 2016 01:42:19

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 MAR 05
DD/MMM/YYYY	
Time of assessment	06:37
hour:min 24-hour clock	
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Do not agree or disagree <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	Do not agree or disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Do not agree or disagree <input type="radio"/>
5. All I want right now is a cigarette	Do not agree or 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: 2146

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (jeanellek1) 18 Jun 2015 14:52:14

Generated On: 20 Jul 2016 01:42:19

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

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

10. I am going to smoke as soon as possible Do not agree or disagree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:15
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
----------------------	------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY6
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W626210
--------------	---------

Actual Collection Date	2014 03 05
------------------------	------------

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: 2146
Folder: Day 6
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:15
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	244.6
Reported Numeric Result	244.6
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: 2146
Folder: Day 6
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:15
Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (jeanellek1) 18 Jun 2015 14:52:15

Generated On: 20 Jul 2016 01:42:19

Sample type

PLASMA

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:15
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001060
Analyte	COT
Sample type	PLASMA
Result	315
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	20
Day of Visit	6
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-05
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:52:15

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:15
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001060
Analyte	NIC
Sample type	PLASMA
Result	7.77
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	20
Day of Visit	6
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-05
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:52:15

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:15
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001061
Analyte	COT
Sample type	PLASMA
Result	282
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	24
Day of Visit	6
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-05
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:52:15

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:15
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001061
Analyte	NIC
Sample type	PLASMA
Result	3.49
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	24
Day of Visit	6
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-05
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (jeanellek1) 18 Jun 2015 14:52:15

Generated On: 20 Jul 2016 01:42:19

Urine End Day

5

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:15
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112520000689
Analyte	COT
Sample type	PLASMA
Result	281
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	6
Celerion Study Number	AA99128-10
Date of Collection	2014-MAR-05
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (jeanellek1) 18 Jun 2015 14:52:15

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 6
Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:15
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112520000689
Analyte	THCOT
Sample type	PLASMA
Result	122
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	6
Celerion Study Number	AA99128-10
Date of Collection	2014-MAR-05
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (jeanellek1) 18 Jun 2015 14:52:15

Generated On: 20 Jul 2016 01:42:19

Urine End Day

6

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Date of Discharge
Data signed: (jeanellek1) 18 Jun 2015 14:52:19
Generated On: 20 Jul 2016 01:42:19

Date of Visit	05 MAR 2014 DD/MMM/YYYY
---------------	----------------------------

Discharge Time	11:34 hour:min 24-hour clock
----------------	---------------------------------

Is the subject continuing in the ambulatory period?	Yes <input checked="" type="radio"/>
---	--------------------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Vital Signs
Data signed: (jeanellek1) 18 Jun 2015 14:52:19
Generated On: 20 Jul 2016 01:42:19

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 10:52
hour:min 24-hour clock

Pulse rate 67
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 116
mmHg

Blood Pressure (diastolic) 62
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Advice on the risk of smoking and debriefing
Data signed: (jeanellek1) 18 Jun 2015 14:52:19
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (8)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (9)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (10)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (11)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (12)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (13)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (14)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (15)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (16)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (17)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (18)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Physical Examination (19)
Data signed: (jeanellek1) 18 Jun 2015 14:52:17
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Weight
Data signed: (jeanellek1) 18 Jun 2015 14:52:20
Generated On: 20 Jul 2016 01:42:19

Measurement(s) assessed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 05 MAR 2014
DD/MMM/YYYY

Time of assessment 08:15
hour:min 24-hour clock

Weight 97.6
kg

BMI 31.7

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 14:52:16
Generated On: 20 Jul 2016 01:42:19

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 65
beats per minute

QRS Interval 99
msec

QT Interval 388
msec

QTcB Interval 403
msec

PR Interval 152
msec

QTcF Interval 398
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 14:52:16
Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Gas Transfer
Data signed: (jeanellek1) 18 Jun 2015 14:52:18
Generated On: 20 Jul 2016 01:42:19

Was the Gas Transfer performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Date of assessment DD/MMM/YYYY 05 MAR 2014

Time of assessment 09:24

DLCO value 30.43
ml/min/mmHg

KCO value 1.54
mmol/min/kPa/L

DLCO/VA value 1.54
mL/min/mmHg/L

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lung Volume Measurements
Data signed: (jeanellek1) 18 Jun 2015 14:52:18
Generated On: 20 Jul 2016 01:42:19

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Date of assessment DD/MMM/YYYY 05 MAR 2014

Time of assessment 09:32

VC value 6.11
L

TLC value 7.98
L

IC value 5.45
L

FRC value 2.53
L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lung Volume Measurements
Data signed: (jeanellek1) 18 Jun 2015 14:52:18
Generated On: 20 Jul 2016 01:42:19

If Not Clinically Significant or Clinically Significant, Please DECREASED FRC AND
specify the finding(s) INCREASED RV

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Spirometry with a short-acting bronchodilator
Data signed: (jeanellek1) 18 Jun 2015 14:52:19
Generated On: 20 Jul 2016 01:42:19

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

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Position SITTING

Date of assessment DD/MMM/YYYY 05 MAR 2014

Time of assessment 10:01

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 5.45 L

Best measured FVC value 5.97 L

Percent of predicted FVC value 109 %

Best measured FEV1 value 4.61 L

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Spirometry with a short-acting bronchodilator
Data signed: (jeanellek1) 18 Jun 2015 14:52:19
Generated On: 20 Jul 2016 01:42:19

Predicted FEV1 value	4.53 L
----------------------	-----------

Percent of predicted FEV1 value	101 %
---------------------------------	----------

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

MEF 25/75 value	3.82 L/s
-----------------	-------------

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

If Abnormal, Clinical Significance	_____
------------------------------------	-------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Haematology
Data signed: (jeanellek1) 18 Jun 2015 14:52:16
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Clinical Chemistry
Data signed: (jeanellek1) 18 Jun 2015 14:52:16
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Urine analysis
Data signed: (jeanellek1) 18 Jun 2015 14:52:16
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: CO Breath Test
Data signed: (jeanellek1) 18 Jun 2015 14:52:16
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	11:00
	hour:min 24-hour clock

Result	4
	ppm

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	82
Reported Numeric Result	82
Reference Range low	44
Reference Range high	249
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W626210
--------------	---------

Actual Collection Date	2014 03 05
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
--------------	-----------------

Lab Test ID	RCT142
-------------	--------

Lab Test Name	FASTING GLUCOSE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	86
Reported Numeric Result	86
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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Actual Collection Time	06:48
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Specimen Condition	<hr/>
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Battery ID	RC272
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Battery Name	TOTAL CHOLESTEROL
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Lab Test ID	RCT20
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	147
Reported Numeric Result	147
Reference Range low	128
Reference Range high	236
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	0.6
Reported Numeric Result	0.6
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.6
Reported Numeric Result	6.6
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	4.3
Reported Numeric Result	4.3
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	RCT1407
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Lab Test Name	ALKALINE PHOSPHATASE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	65
Reported Numeric Result	65
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	129
Reported Numeric Result	129
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	RCT15
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Lab Test Name	SERUM SODIUM
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	141
Reported Numeric Result	141
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	RCT16
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Lab Test Name	SERUM POTASSIUM
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	4.1
Reported Numeric Result	4.1
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	0.1
Reported Numeric Result	0.1
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	RCT3
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Lab Test Name	GGT
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	16
Reported Numeric Result	16
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	RCT392
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Lab Test Name	CREATININE (RATE BLANKED)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	1.0
Reported Numeric Result	1.0
Reference Range low	0.5
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	19
Reported Numeric Result	19
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	RCT5
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Lab Test Name	AST (SGOT)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	23
Reported Numeric Result	23
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
------------------------	------------

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	11
Reported Numeric Result	11
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	HMT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.38
Reported Numeric Result	0.38
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	HMT100
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.09
Reported Numeric Result	0.09
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT12

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.03
Reported Numeric Result	0.03
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	HMT13
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	HMT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	55.0
Reported Numeric Result	55.0
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	37.0
Reported Numeric Result	37.0
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT17

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.1
Reported Numeric Result	6.1
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.5
Reported Numeric Result	1.5
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	HMT19
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input 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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	HMT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	44
Reported Numeric Result	44
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	HMT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	RBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.8
Reported Numeric Result	4.8
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	92
Reported Numeric Result	92
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	15.0
Reported Numeric Result	15.0
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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	HMT7
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.23
Reported Numeric Result	6.23
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
------------------------	------------

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	HMT71
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

Actual Collection Time 06:48

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT8

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	3.42
Reported Numeric Result	3.42
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
--------------	---------

Actual Collection Date	2014 03 05
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT9
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	2.31
Reported Numeric Result	2.31
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
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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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	1.022
Reported Numeric Result	1.022
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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W626210

Actual Collection Date 2014 03 05

Actual Collection Time 06:48

Specimen Condition _____


Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT3

Lab Test Name UR PH

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	6.0
Reported Numeric Result	6.0
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
------------------------	------------

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
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Actual Collection Date	2014 03 05
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT49
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Lab Test Name	UR PROTEIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

Test ID _____

Test Status Done 

Reported Text Result TRACE

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
--------------	---------

Actual Collection Date	2014 03 05
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

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	UAT5
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Lab Test Name	UR GLUCOSE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W626210
--------------	---------

Actual Collection Date	2014 03 05
------------------------	------------

Actual Collection Time	06:48
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT7
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Lab Test Name	UR BILIRUBIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Confinement)
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 14:52:22
Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Day 30

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:52:44

Generated On: 20 Jul 2016 01:42:19

Visit Not Done	False
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If Not Done, Specify Reason	<hr/>
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Date of Visit	29 MAR 2014 DD/MMM/YYYY
---------------	----------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Vital Signs

Data signed: (jeanellek1) 18 Jun 2015 14:52:44

Generated On: 20 Jul 2016 01:42:19

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

29 MAR 2014
DD/MMM/YYYY

Time of assessment

14:54
hour:min 24-hour clock

Pulse rate

73
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

112
mmHg

Blood Pressure (diastolic)

65
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Advice on the risk of smoking and debriefing
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Date	29 MAR 2014 DD/MMM/YYYY
------	----------------------------

Has the subject received advices on the risks of smoking?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Has a debriefing been performed about THS 2.2?	Yes <input checked="" type="radio"/>
--	--------------------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Physical Examination
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

29 MAR 2014
DD/MMM/YYYY

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Physical Examination (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (8)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (9)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (10)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (11)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (12)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (13)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (14)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (15)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (16)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (17)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (18)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146
Folder: Day 30
Form: Physical Examination (19)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 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: 2146

Folder: Day 30

Form: Weight

Data signed: (jeanellek1) 18 Jun 2015 14:52:44

Generated On: 20 Jul 2016 01:42:19

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

29 MAR 2014
DD/MMM/YYYY

Time of assessment

15:17
hour:min 24-hour clock

Weight

95.4
kg

BMI

31.0

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 29 MAR 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 73
beats per minute

QRS Interval 98
msec

QT Interval 365
msec

QTcB Interval 404
msec

PR Interval 134
msec

QTcF Interval 390
msec

Interpretation Normal ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (jeanellek1) 18 Jun 2015 14:52:41

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Haematology
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Clinical Chemistry
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Day 30

Form: Urine analysis

Data signed: (jeanellek1) 18 Jun 2015 14:52:41

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Plasma Nicotine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	29 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	10:46
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Plasma Cotinine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	29 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	10:46
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: CoHb Blood Sample <D30_D60>
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	29 MAR 2014
---------------------	-------------

Timepoint	10:00 - 11:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	10:46
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: CO Breath Test

Data signed: (jeanellek1) 18 Jun 2015 14:52:41

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Actual Date of Assessment	29 MAR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Actual Time of Assessment	10:48 hour:min 24-hour clock
---------------------------	---------------------------------

Result	6 ppm
--------	----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1
Data signed: (jeanellek1) 18 Jun 2015 14:52:41
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	30 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:31
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: 24 hour urine collections
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Start Date	29 MAR 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	09:26 hour:min 24-hour clock
------------	---------------------------------

End Date	30 MAR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	08:33 hour:min 24-hour clock
----------	---------------------------------

Volume	4753 mL
--------	------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Sample Urine Collection
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Were samples for 24h collected? Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected? 13

How many back up tubes were collected? 13

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V968781
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
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Lab Test ID	RCT19
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Lab Test Name	TRIGLYCERIDES (GPO)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	127
Reported Numeric Result	127
Reference Range low	44
Reference Range high	249
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V968781
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Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
--------------	-----------------

Lab Test ID	RCT142
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Lab Test Name	FASTING GLUCOSE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	93
Reported Numeric Result	93
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V968781

Actual Collection Date 2014 03 30

Actual Collection Time 06:31

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	132
Reported Numeric Result	132
Reference Range low	128
Reference Range high	236
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1
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Lab Test Name	TOTAL BILIRUBIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	0.3
Reported Numeric Result	0.3
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	6.6
Reported Numeric Result	6.6
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V968781
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Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT13
-------------	-------

Lab Test Name	ALBUMIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	4.2
Reported Numeric Result	4.2
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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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	RCT1407
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Lab Test Name	ALKALINE PHOSPHATASE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	64
Reported Numeric Result	64
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
------------------------	-------

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	129
Reported Numeric Result	129
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (8)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT15
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Lab Test Name	SERUM SODIUM
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	141
Reported Numeric Result	141
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (9)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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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	RCT16
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Lab Test Name	SERUM POTASSIUM
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	4.3
Reported Numeric Result	4.3
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (10)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	<0.1
Reported Numeric Result	
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (11)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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Lab Test Name	GGT
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	22
Reported Numeric Result	22
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (12)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT392
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Lab Test Name	CREATININE (RATE BLANKED)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	1.0
Reported Numeric Result	1.0
Reference Range low	0.5
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (13)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (14)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID V968781

Actual Collection Date 2014 03 30

Actual Collection Time 06:31

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	28
Reported Numeric Result	28
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (15)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	9
Reported Numeric Result	9
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (16)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.40
Reported Numeric Result	0.40
Reference Range low	0.12
Reference Range high	0.92
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (17)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT100
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	32
Reported Numeric Result	32
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (18)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT102
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (19)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT11
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.08
Reported Numeric Result	0.08
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (20)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input 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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.02
Reported Numeric Result	0.02
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (21)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT13
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	237
Reported Numeric Result	237
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (22)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	50.7
Reported Numeric Result	50.7
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (23)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	39.9
Reported Numeric Result	39.9
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (24)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.6
Reported Numeric Result	7.6
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (25)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT18
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.5
Reported Numeric Result	1.5
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (26)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19


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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V968781

Actual Collection Date 2014 03 30

Actual Collection Time 06:31

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT19

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (27)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	46
Reported Numeric Result	46
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (28)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.9
Reported Numeric Result	4.9
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (29)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	93
Reported Numeric Result	93
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (30)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.7
Reported Numeric Result	15.7
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (31)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT7
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	5.35
Reported Numeric Result	5.35
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (32)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT71
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (33)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	2.71
Reported Numeric Result	2.71
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (34)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
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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	HMT9
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.13
Reported Numeric Result	2.13
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (35)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V968781
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (36)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V968781
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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

Lab Test Name	UR SPECIFIC GRAVITY
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	1.004
Reported Numeric Result	1.004
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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (37)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
-----------------------	---

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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

Lab Test Name	UR PH
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	5.5
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Reported Numeric Result	5.5
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Reference Range low	5.0
---------------------	-----

Reference Range high	8.0
----------------------	-----

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (38)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (39)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

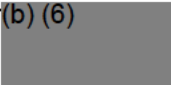
Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
-----------------------	---

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V968781
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT49
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Lab Test Name	UR PROTEIN
---------------	------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (40)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
-----------------------	---

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT5
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Lab Test Name	UR GLUCOSE
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (41)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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) (6) 
-----------------------	---

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V968781
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT7
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Lab Test Name	UR BILIRUBIN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_CCLS (42)
Data signed: (jeanellek1) 18 Jun 2015 14:52:47
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Lab_BU_COHB (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:00
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115150003549
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.70
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	10
Day of Visit	30
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-29
Timepoint-minutes	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Cough Assessment (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment 06:01
hour:min 24-hour clock

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs? No ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you? _____

Second Question: Cough Intensity Scale:
How intense is your cough? _____

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day? _____

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (jeanellek1) 18 Jun 2015 14:52:43

Generated On: 20 Jul 2016 01:42:19

Are there any other important observations that you
would like to share with us about you coughing? (open
question)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (jeanellek1) 18 Jun 2015 14:52:43

Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment
DD/MMM/YYYY

30 MAR 2014
DD/MMM/YYYY

Time of assessment

06:01
hour:min 24-hour clock

Please indicate for each of the items below, how you have been feeling over the past 24 hours

Result

1. Angry, irritable, frustrated

None

2. Anxious, tense

None

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:52:43

Generated On: 20 Jul 2016 01:42:19

	Result
3. Depressed Mood, sad	None
4. Desire or craving to smoke	Moderate
5. Difficulty concentrating	Moderate
6. Increased appetite, hungry, weight gain	Moderate
7. Insomnia, sleep problems, awakening at night	None
8. Restless	Mild
9. Impatient	Slight

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (jeanellek1) 18 Jun 2015 14:52:43

Generated On: 20 Jul 2016 01:42:19

	Result
10. Constipation	None
11. Dizziness	None
12. Coughing	None
13. Dreaming or nightmares	Moderate
14. Nausea	None
15. Sore throat	None

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:52:44

Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

STAFF INADVERTENTLY
FAILED TO HAVE THE
SUBJECT COMPLETE THE
QUESTIONNAIRE. PLEASE
REFERENCE E-NOTE 1138856.

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: 2146
Folder: Day 30
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	29 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:22 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input type="radio"/>
--	--

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Neither agree nor disagree <input type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input type="radio"/>
--	--

If you agree or strongly agree, please describe :	<hr/>
---	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

4. The device is easy to use.

Agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Neither agree nor disagree ☐

If you agree or strongly agree, please describe : _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Questionnaire on smoking urges (QSU) (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

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

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

Date of assessment	29 MAR 2014
DD/MMM/YYYY	

Time of assessment	20:21
hour:min 24-hour clock	

1. I have a desire for a cigarette right now	Do not agree or disagree <input checked="" type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input checked="" type="radio"/>
---	---

3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Do not agree or disagree <input checked="" type="radio"/>
---	---

5. All I want right now is a cigarette	Do not agree or disagree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Do not agree or disagree <input checked="" type="radio"/>
-----------------------------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Questionnaire on smoking urges (QSU) (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

7. A cigarette would taste good now Do not agree or disagree ☐

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

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

10. I am going to smoke as soon as possible Do not agree or disagree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done

Date of assessment 29 MAR 2014
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Was smoking satisfying? ☒

Response Moderately ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did cigarettes taste good? ☒

Response Moderately ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did you enjoy the sensation in your throat and chest? ☒

Response Moderately ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did smoking calm you down? ☒

Response Moderately ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking make you feel more awake? ☐

Response Moderately ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking make you feel less irritable? ☐

Response Moderately ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking help you concentrate? ☒

Response Moderately ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking reduce your hunger for food? ☐

Response Little ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did smoking make you dizzy? ☐

Response Not at all ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did smoking make you
nauseous? ☐

Response Not at all ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking immediately relieve your craving for a cigarette? ☒

Response Little ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)
Data signed: (jeanellek1) 18 Jun 2015 14:52:43
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 29 MAR 2014
DD/MMM/YYYY

Time of assessment 20:21
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did you enjoy smoking? ☒

Response A lot ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY30
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
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Actual Collection Time	06:31
------------------------	-------

Specimen Condition	
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Battery ID	RC6871
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Battery Name	HDL
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Lab Test ID	RCT1684
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	45
Reported Numeric Result	45
Reference Range low	30
Reference Range high	63
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	2146
----------------------	------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Lab Test Name	C-REACTIVE PROTEIN (N HS)-QT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.101
Reported Numeric Result	0.101
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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY30
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
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Specimen Condition	
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Battery ID	CG267
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Battery Name	FIBRINOGEN
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Lab Test ID	CGT285
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Lab Test Name	FIBRINOGEN
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	251
Reported Numeric Result	251
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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
----------------------	------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	
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Battery ID	CN236
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Battery Name	HOMOCYSTEINE
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Lab Test ID	CNT145
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Lab Test Name	HOMOCYSTEINE, EDTAPL
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	9.76
Reported Numeric Result	9.76
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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY30
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
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Specimen Condition	
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Battery ID	IM2293
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Battery Name	SICAM-1
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Lab Test ID	IMT1768
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Lab Test Name	SICAM-1-RUO
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	273.2
Reported Numeric Result	273.2
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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	2146
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY30
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V968781
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Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	06:31
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Specimen Condition	
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Battery ID	RC9267
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Battery Name	LDL
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Lab Test ID	RCT2394
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Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

Test ID	
Test Status	Done 
Reported Text Result	68
Reported Numeric Result	68
Reference Range low	66
Reference Range high	147
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: 2146
Folder: Day 30
Form: Risk Markers(CCLS) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:52:44
Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:01
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003723
Analyte	HPMA
Sample type	URINE
Result	156
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:01
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003723
Analyte	CEMA
Sample type	URINE
Result	15.1
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:53:01
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112450003723
Analyte	HBMA
Sample type	URINE
Result	36.3
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (NNN, NNAL) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:00
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004486
Analyte	NNAL
Sample type	URINE
Result	33.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (NNN, NNAL) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:00
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112460004486
Analyte	NNN
Sample type	URINE
Result	0.897
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (HEMA)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (HEMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:00
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112470002242
Analyte	HEMA
Sample type	URINE
Result	1.31
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

(1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000823
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Analyte	COT
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Sample type	URINE
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Result	886
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-29
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Timepoint-minutes	
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Urine Start Day	30
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000823
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Analyte	COT-GLUC
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Sample type	URINE
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Result	1790
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-29
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Timepoint-minutes	
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Urine Start Day	30
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

(3)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000823
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Analyte	NIC
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Sample type	URINE
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Result	214
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-29
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Timepoint-minutes	
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Urine Start Day	30
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

(4)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000823
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Analyte	NIC-GLUC
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Sample type	URINE
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Result	229
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-29
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Timepoint-minutes	
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Urine Start Day	30
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

(5)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000823
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Analyte	THCOT
---------	-------

Sample type	URINE
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Result	2130
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-29
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Timepoint-minutes	
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Urine Start Day	30
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

(6)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112480000823
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Analyte	THCOT-GLUC
---------	------------

Sample type	URINE
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Result	652
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-06
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Date of Collection	2014-MAR-29
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Timepoint-minutes	
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Urine Start Day	30
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (3-OH BaP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:01
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112490002242
Analyte	3-OH BAP
Sample type	URINE
Result	BLQ<(25.0)
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-07
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:02

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:02
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002264
Analyte	1-NA
Sample type	URINE
Result	4.59
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:02

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:02
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002264
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:02

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:53:02
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002264
Analyte	4-ABP
Sample type	URINE
Result	1.79
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:53:02

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:53:02
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112510002264
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:02

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (11-dTXb2) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:00
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112530001636
Analyte	11-DTXB2
Sample type	URINE
Result	161
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-11
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (iPF2a-III) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:00
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112540001706
Analyte	IPF2A-III
Sample type	URINE
Result	160
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-12
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (1-OHP)

Data signed: (jeanellek1) 18 Jun 2015 14:53:03

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (1-OHP) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:03
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115190004156
Analyte	1-OHP
Sample type	URINE
Result	28.6
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:03

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (SPMA, SBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:00
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004147
Analyte	SBMA
Sample type	URINE
Result	0.906
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (SPMA, SBMA) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:00
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115170004147
Analyte	SPMA
Sample type	URINE
Result	0.371
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:53:00

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (MHBMA)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (MHBMA) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:01
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115180004156
Analyte	MHBMA
Sample type	URINE
Result	BLQ<(0.100)
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (Creatinine)

Data signed: (jeanellek1) 18 Jun 2015 14:53:02

Generated On: 20 Jul 2016 01:42:19

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Urine (Creatinine) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:02
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05115160002220
Analyte	CREATININE
Sample type	URINE
Result	31.8
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	30

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:02

Generated On: 20 Jul 2016 01:42:19

Urine End Day	31
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Sample type

PLASMA

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:01
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001062
Analyte	COT
Sample type	PLASMA
Result	231
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-29
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	30
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 30
Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:01
Generated On: 20 Jul 2016 01:42:19

Sample Barcode	05112430001062
Analyte	NIC
Sample type	PLASMA
Result	11.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-29
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (jeanellek1) 18 Jun 2015 14:53:01

Generated On: 20 Jul 2016 01:42:19

Urine End Day	30
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: Date of Visit

Data signed: (jeanellek1) 18 Jun 2015 14:53:09

Generated On: 20 Jul 2016 01:42:19

Visit Not Done	True
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If Not Done, Specify Reason	SUBJECT DID NOT CHECK IN FOR THIS VISIT
-----------------------------	--

Date of Visit	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: Vital Signs

Data signed: (jeanellek1) 18 Jun 2015 14:53:09

Generated On: 20 Jul 2016 01:42:19

Were Vitals Signs assessed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

Has the subject smoked within 15 minutes prior to
assessment

Time of assessment

Pulse rate

Respiratory rate

Blood Pressure (systolic)

Blood Pressure (diastolic)

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: Advice on the risk of smoking and debriefing

Data signed: (jeanellek1) 18 Jun 2015 14:53:09

Generated On: 20 Jul 2016 01:42:19

Has the subject received advices on the risks of
smoking? _____

Has a debriefing been performed about THS 2.2? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: Physical Examination

Data signed: (jeanellek1) 18 Jun 2015 14:53:06

Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

General Appearance ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

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

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (3)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Thyroid Gland ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (4)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Heart ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (5)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Chest ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (6)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Lungs ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (7)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Gastrointestinal ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (8)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Cardiovascular System ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (9)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Neurologic ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (10)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Skin ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (11)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Back ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (12)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Musculoskeletal ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (13)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Abdomen ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (14)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Dentition ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (15)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Other ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (16)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Other ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (17)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Other ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (18)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Other ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Physical Examination (19)
Data signed: (jeanellek1) 18 Jun 2015 14:53:06
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Other ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: Weight

Data signed: (jeanellek1) 18 Jun 2015 14:53:09

Generated On: 20 Jul 2016 01:42:19

Measurement(s) assessed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

Time of assessment

Weight

BMI

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 14:53:04
Generated On: 20 Jul 2016 01:42:19

Was the ECG performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

Position

Supine ☒

Heart Rate

QRS Interval

QT Interval

QTcB Interval

PR Interval

QTcF Interval

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: 2146

Folder: Day 60

Form: Haematology

Data signed: (jeanellek1) 18 Jun 2015 14:53:05

Generated On: 20 Jul 2016 01:42:19

Were samples collected?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

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: 2146
Folder: Day 60
Form: Clinical Chemistry
Data signed: (jeanellek1) 18 Jun 2015 14:53:05
Generated On: 20 Jul 2016 01:42:19

Were samples collected?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

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: 2146

Folder: Day 60

Form: Urine analysis

Data signed: (jeanellek1) 18 Jun 2015 14:53:05

Generated On: 20 Jul 2016 01:42:19

Were samples collected?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Plasma Nicotine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:53:05
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Plasma Cotinine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:53:05
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: CoHb Blood Sample <D30_D60>
Data signed: (jeanellek1) 18 Jun 2015 14:53:05
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

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

Timepoint	10:00 - 11:30 <input checked="" type="radio"/>
-----------	--

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: CO Breath Test

Data signed: (jeanellek1) 18 Jun 2015 14:53:04

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

Actual Time of Assessment	<hr/>
---------------------------	-------

Result	<hr/>
--------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1
Data signed: (jeanellek1) 18 Jun 2015 14:53:05
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: 24 hour urine collections
Data signed: (jeanellek1) 18 Jun 2015 14:53:09
Generated On: 20 Jul 2016 01:42:19

Start Date	
Start Time	
End Date	
End Time	
Volume	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Sample Urine Collection
Data signed: (jeanellek1) 18 Jun 2015 14:53:09
Generated On: 20 Jul 2016 01:42:19

Were samples for 24h collected?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

How many primary tubes were collected? _____

How many back up tubes were collected? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Cough Assessment (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☐

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment
DD/MMM/YYYY

Time of assessment

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

Second Question: Cough Intensity Scale:
How intense is your cough?

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: Cough Assessment (Paper)

Data signed: (jeanellek1) 18 Jun 2015 14:53:07

Generated On: 20 Jul 2016 01:42:19

Are there any other important observations that you
would like to share with us about you coughing? (open
question)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (jeanellek1) 18 Jun 2015 14:53:08

Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN FOR THIS VISIT

Date of assessment
DD/MMM/YYYY

Time of assessment

Please indicate for each of the items below, how you have been feeling over the past 24 hours

Result

1. Angry, irritable, frustrated

2. Anxious, tense

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:53:08

Generated On: 20 Jul 2016 01:42:19

Result

3. Depressed Mood, sad

4. Desire or craving to smoke

5. Difficulty concentrating

6. Increased appetite, hungry, weight gain

7. Insomnia, sleep problems, awakening at night

8. Restless

9. Impatient

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (jeanellek1) 18 Jun 2015 14:53:08

Generated On: 20 Jul 2016 01:42:19

Result

10. Constipation

11. Dizziness

12. Coughing

13. Dreaming or nightmares

14. Nausea

15. Sore throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:09

Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☐

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

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: 2146
Folder: Day 60
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:53:09
Generated On: 20 Jul 2016 01:42:19

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	No <input checked="" type="radio"/>
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Reason not done	SUBJECT DID NOT CHECK IN FOR THIS VISIT
-----------------	--

Date of assessment	_____
--------------------	-------

Time of assessment	_____
--------------------	-------

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: 2146
Folder: Day 60
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:53:09
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 60
Form: Questionnaire on smoking urges (QSU) (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:53:09
Generated On: 20 Jul 2016 01:42:19

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

Was paper questionnaire used?	No <input type="radio"/>
-------------------------------	--------------------------

Reason not done	SUBJECT DID NOT CHECK IN FOR THIS VISIT
-----------------	--

Date of assessment

DD/MMM/YYYY

Time of assessment

hour:min 24-hour clock

1. I have a desire for a cigarette right now

2. Nothing would be better than smoking a cigarette
right now

3. If it were possible I would probably smoke now

4. I could control things better right now if I could smoke

5. All I want right now is a cigarette

6. I have an urge for a cigarette

7. A cigarette would taste good now

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 60

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (jeanellek1) 18 Jun 2015 14:53:09

Generated On: 20 Jul 2016 01:42:19

8. I would do almost anything for a cigarette now

9. Smoking would make me less depressed

10. I am going to smoke as soon as possible

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? No ☒

Reason not done SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Was smoking satisfying? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? No ☒

Reason not done SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did cigarettes taste good? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did you enjoy the ☒
sensation in your throat
and chest?

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? No ☒

Reason not done SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking calm you
down? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you feel ☒
more awake?

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you feel ☒
less irritable?

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? No ☒

Reason not done SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking help you ☒
concentrate?

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? No ☒

Reason not done SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking reduce your ☒
hunger for food?

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you
dizzy? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? No ☒

Reason not done SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you
nauseous? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? No ☒

Reason not done SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking immediately ☒
relieve your craving for a
cigarette?

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 60
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)
Data signed: (jeanellek1) 18 Jun 2015 14:53:07
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did you enjoy smoking? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Date of Visit
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

Visit Not Done	True
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If Not Done, Specify Reason	SUBJECT DID NOT CHECK IN FOR THIS VISIT
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Date of Visit	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Plasma Nicotine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

Date DD/MMM/YYYY	
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Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Plasma Cotinine Sample
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

Date DD/MMM/YYYY	
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Time hour:min 24-hour clock	
--------------------------------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: CoHb Blood Sample <D90>
Data signed: (jeanellek1) 18 Jun 2015 14:53:09
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

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

Timepoint	10:00 - 12:30 <input checked="" type="radio"/>
-----------	--

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 90

Form: Oxysterols

Data signed: (jeanellek1) 18 Jun 2015 14:53:10

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

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: 2146

Folder: Day 90

Form: CO Breath Test

Data signed: (jeanellek1) 18 Jun 2015 14:53:09

Generated On: 20 Jul 2016 01:42:19

Assessment not done	True
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If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
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Actual Time of Assessment	<hr/>
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Result	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 90

Form: CYP2A6 activity Sample

Data signed: (jeanellek1) 18 Jun 2015 14:53:10

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:

SUBJECT DID NOT CHECK IN FOR THIS VISIT

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
--	---	-----------

		trans-3'-hydroxyc otinine
--	--	------------------------------

		cotinine
--	--	----------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 90

Form: CYP1A2 activity Sample

Data signed: (jeanellek1) 18 Jun 2015 14:53:10

Generated On: 20 Jul 2016 01:42:19

Time of caffeine tablet intake

Sample collection Not Done

True

If Not Done, please specify the reason:

SUBJECT DID NOT CHECK IN FOR THIS VISIT

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: 2146

Folder: Day 90

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:10

Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: 24 hour urine collections
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

Start Date	
Start Time	
End Date	
End Time	
Volume	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Sample Urine Collection
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

Were samples for 24h collected?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

How many primary tubes were collected? _____

How many back up tubes were collected? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: 4 hour urine collection
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

Start Date	<hr/>
Start Time	<hr/>
End Time	<hr/>
Volume	<hr/>

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Sample Urine Collection (4 Hour collection)
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

Were samples for 4h collected?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

How many primary tubes were collected? _____

How many back up tubes were collected? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Bio-banking (Transcriptomics)
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Day 90

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (jeanellek1) 18 Jun 2015 14:53:12

Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Day 90

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (jeanellek1) 18 Jun 2015 14:53:12

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 90
Form: Cough Assessment (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☐

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment
DD/MMM/YYYY

Time of assessment

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

Second Question: Cough Intensity Scale:
How intense is your cough?

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 90

Form: Cough Assessment (Paper)

Data signed: (jeanellek1) 18 Jun 2015 14:53:10

Generated On: 20 Jul 2016 01:42:19

Are there any other important observations that you
would like to share with us about you coughing? (open
question)

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 90

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (jeanellek1) 18 Jun 2015 14:53:10

Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN FOR THIS VISIT

Date of assessment
DD/MMM/YYYY

Time of assessment

Please indicate for each of the items below, how you have been feeling over the past 24 hours

Result

1. Angry, irritable, frustrated

2. Anxious, tense

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 90

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (jeanellek1) 18 Jun 2015 14:53:10

Generated On: 20 Jul 2016 01:42:19

Result

3. Depressed Mood, sad

4. Desire or craving to smoke

5. Difficulty concentrating

6. Increased appetite, hungry, weight gain

7. Insomnia, sleep problems, awakening at night

8. Restless

9. Impatient

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 90

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (jeanellek1) 18 Jun 2015 14:53:10

Generated On: 20 Jul 2016 01:42:19

Result

10. Constipation

11. Dizziness

12. Coughing

13. Dreaming or nightmares

14. Nausea

15. Sore throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 90

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

Data signed: (jeanellek1) 18 Jun 2015 14:53:12

Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

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: 2146
Folder: Day 90
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
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Was paper questionnaire used?	No <input checked="" type="radio"/>
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Reason not done	SUBJECT DID NOT CHECK IN FOR THIS VISIT
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Date of assessment	_____
--------------------	-------

Time of assessment	_____
--------------------	-------

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: 2146
Folder: Day 90
Form: Human Smoking Topography Questionnaire
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Day 90
Form: Questionnaire on smoking urges (QSU) (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

Was paper questionnaire used?	No <input type="radio"/>
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Reason not done	SUBJECT DID NOT CHECK IN FOR THIS VISIT
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Date of assessment

DD/MMM/YYYY

Time of assessment

hour:min 24-hour clock

1. I have a desire for a cigarette right now

2. Nothing would be better than smoking a cigarette
right now

3. If it were possible I would probably smoke now

4. I could control things better right now if I could smoke

5. All I want right now is a cigarette

6. I have an urge for a cigarette

7. A cigarette would taste good now

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Day 90

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (jeanellek1) 18 Jun 2015 14:53:12

Generated On: 20 Jul 2016 01:42:19

8. I would do almost anything for a cigarette now

9. Smoking would make me less depressed

10. I am going to smoke as soon as possible

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Was smoking satisfying? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did cigarettes taste good? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? No ☒

Reason not done SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did you enjoy the
sensation in your throat
and chest? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking calm you
down? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you feel ☒
more awake?

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? No ☒

Reason not done SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you feel ☒
less irritable?

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking help you
concentrate? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking reduce your ☒
hunger for food?

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you
dizzy? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you
nauseous? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking immediately ☒
relieve your craving for a
cigarette?

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT DID NOT CHECK IN
FOR THIS VISIT

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did you enjoy smoking? ☒

Response

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Day 90
Form: FTND Questionnaire (FTND) (Paper)
Data signed: (jeanellek1) 18 Jun 2015 14:53:10
Generated On: 20 Jul 2016 01:42:19

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

Was paper questionnaire used?	No <input type="radio"/>
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Reason not done	SUBJECT DID NOT CHECK IN FOR THIS VISIT
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Date of assessment DD/MMM/YYYY	<hr/>
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Time of assessment	<hr/>
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1. How soon after you wake up do you smoke your first cigarette?	<hr/>
--	-------

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	<hr/>
--	-------

3. Which cigarette would you hate most to give up?	<hr/>
--	-------

4. How many cigarettes per day do you smoke?	<hr/>
--	-------

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?	<hr/>
---	-------

6. Do you smoke even if you are so ill that you are in bed most of the day?	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Date of Discharge
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of Visit

Discharge Time

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Vital Signs
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Were Vitals Signs assessed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

Has the subject smoked within 15 minutes prior to
assessment

Time of assessment

Pulse rate

Respiratory rate

Blood Pressure (systolic)

Blood Pressure (diastolic)

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Advice on the risk of smoking and debriefing
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Has the subject received advices on the risks of smoking?

No ☒

Has a debriefing been performed about THS 2.2?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

General Appearance ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

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

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (3)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Thyroid Gland ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (4)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Heart ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (5)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Chest ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (6)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Lungs ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (7)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Gastrointestinal ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (8)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Cardiovascular System ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (9)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Neurologic ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (10)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Skin ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (11)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Back ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (12)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Musculoskeletal ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (13)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Abdomen ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (14)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Dentition ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (15)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Other ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (16)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Other ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (17)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Other ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (18)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Other ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Physical Examination (19)
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Was the physical examination performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

System

Other ☒

Outcome

Abnormal, please specify

Clinically significant

Not Done

False

Not Done; please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: Weight
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Measurement(s) assessed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

Time of assessment

Weight

BMI

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: ECG (12-Lead Standard)
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

Was the ECG performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

Position

Supine ☒

Heart Rate

QRS Interval

QT Interval

QTcB Interval

PR Interval

QTcF Interval

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: 2146
Folder: Discharge (Ambulatory)
Form: Gas Transfer
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Was the Gas Transfer performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

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: 2146
Folder: Discharge (Ambulatory)
Form: Lung Volume Measurements
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Were the Lung Volume Measurements performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

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: 2146
Folder: Discharge (Ambulatory)
Form: Spirometry with a short-acting bronchodilator
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Was the Spirometry with a short-acting bronchodilator performed?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

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: 2146
Folder: Discharge (Ambulatory)
Form: Spirometry with a short-acting bronchodilator
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Discharge (Ambulatory)
Form: Haematology
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Were samples collected?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

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: 2146
Folder: Discharge (Ambulatory)
Form: Clinical Chemistry
Data signed: (jeanellek1) 18 Jun 2015 14:53:12
Generated On: 20 Jul 2016 01:42:19

Were samples collected?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

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: 2146
Folder: Discharge (Ambulatory)
Form: Urine analysis
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

Were samples collected?

No ☒

If No, please specify the reason:

SUBJECT DID NOT COME IN
FOR VISIT, DID NOT
RESPOND TO PHONE CALLS

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Discharge (Ambulatory)
Form: CoHb Blood Sample <prior to gas transfer and product>
Data signed: (jeanellek1) 18 Jun 2015 14:53:13
Generated On: 20 Jul 2016 01:42:19

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

If Not Done, please specify the reason:	SUBJECT DID NOT CHECK IN FOR THIS VISIT
---	--

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: 2146
Folder: Product Use
Form: Product administration-mCC
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
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Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:32
----------------------	-------

Time of butt return	06:40
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
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Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:19
----------------------	-------

Time of butt return	07:27
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (3)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
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Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:52
----------------------	-------

Time of butt return	08:00
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:50
----------------------	-------

Time of butt return	08:59
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (5)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:25
----------------------	-------

Time of butt return	09:35
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (6)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:36
----------------------	-------

Time of butt return	10:46
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (7)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
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Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:24
----------------------	-------

Time of butt return	12:35
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (8)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:22
----------------------	-------

Time of butt return	13:31
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	14:39
----------------------	-------

Time of butt return	14:46
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (10)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
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Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:23
----------------------	-------

Time of butt return	15:31
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (11)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:19
----------------------	-------

Time of butt return	16:26
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (12)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
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Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:53
----------------------	-------

Time of butt return	18:01
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (13)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:13
----------------------	-------

Time of butt return	19:21
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (14)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:15
----------------------	-------

Time of butt return	09:26
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	08DL0216COHG10218001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (15)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:24
----------------------	-------

Time of butt return	10:33
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	08DL0216COHG10218002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (16)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:23
----------------------	-------

Time of butt return	12:31
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	08DL0216COHG10218003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (17)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:38
----------------------	-------

Time of butt return	13:45
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	08DL0216COHG10218004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (18)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:12
----------------------	-------

Time of butt return	15:22
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	08DL0216COHG10218005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (19)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:20
----------------------	-------

Time of butt return	16:28
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	08DL0216COHG10218006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (20)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:20
----------------------	-------

Time of butt return	17:26
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	_____
-------------------	-------

Comment	FAILED TO START DEVICE DURING EVENT
---------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (21)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:52
----------------------	-------

Time of butt return	19:01
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	08DL0216COHG10218007
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (22)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:48
----------------------	-------

Time of butt return	19:58
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	08DL0216COHG10218008
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (23)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:59
----------------------	-------

Time of butt return	20:10
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	_____
-------------------	-------

Comment	SUBJECT SAID IT TURNED OFF DURING EVENT
---------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (24)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:03
----------------------	-------

Time of butt return	21:14
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	218
----------------------------	-----

SODIM file number	08DL0216COHG10218009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (25)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:54
----------------------	-------

Time of butt return	20:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (26)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:35
----------------------	-------

Time of butt return	20:43
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-mCC (27)
Data signed: (jeanellek1) 18 Jun 2015 14:53:14
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:29
----------------------	-------

Time of butt return	21:37
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (jeanellek1) 18 Jun 2015 14:53:14

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	25 FEB 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:29
----------------------	-------

Time of product return	16:32
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	_____
-------------------------	-------

Tobacco plug vial number	_____
--------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
--------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:31
----------------------	-------

Time of product return	06:37
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	08DL0216COHG11016001
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B-08545
--------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (2)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (3)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:13
----------------------	-------

Time of product return	07:22
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	08DL0216COHG11016002
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B-08545
--------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (3)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (4)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
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Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:21
----------------------	-------

Time of product return	08:29
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	SUBJECT FAILED TO START DEVICE AT BEGINNING OF EVENT
---------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (4)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

Batch Number

B-08545

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: 2146

Folder: Product Use

Form: Product administration-THS menthol (5)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
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Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	08:44
----------------------	-------

Time of product return	08:53
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	08DL0216COHG11016003
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Comment	
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (5)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (6)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
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Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:35
----------------------	-------

Time of product return	12:42
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	08DL0216COHG11016004
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (6)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (7)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
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Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:15
----------------------	-------

Time of product return	13:24
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	08DL0216COHG11016005
-------------------	----------------------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (7)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (8)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:38
----------------------	-------

Time of product return	14:50
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	SUBJECT FAILED TO START DEVICE AT BEGINNING OF EVENT
---------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (8)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

Batch Number

B-08545

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (9)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
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Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:44
----------------------	-------

Time of product return	15:53
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	08DL0216COHG11016006
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (9)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (10)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:18
----------------------	-------

Time of product return	17:29
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	08DL0216COHG11016007
-------------------	----------------------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (10)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (11)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
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Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:35
----------------------	-------

Time of product return	17:44
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	08DL0216COHG11016008
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (11)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (12)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:57
----------------------	-------

Time of product return	19:05
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	THS DVEICE DID NOT RECORD
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (12)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (13)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:49
----------------------	-------

Time of product return	19:56
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	08DL0216COHG11016009
-------------------	----------------------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (13)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (14)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	28 FEB 2014
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Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:01
----------------------	-------

Time of product return	21:09
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	08DL0216COHG11016010
-------------------	----------------------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (14)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (15)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:32
----------------------	-------

Time of product return	06:39
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (15)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (16)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:08
----------------------	-------

Time of product return	07:16
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (16)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (17)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:46
----------------------	-------

Time of product return	07:52
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (17)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (18)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:15
----------------------	-------

Time of product return	08:22
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (18)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (19)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:48
----------------------	-------

Time of product return	08:50
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (19)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (20)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:56
----------------------	-------

Time of product return	09:03
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (20)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (21)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:40
----------------------	-------

Time of product return	09:46
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (21)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (22)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:21
----------------------	-------

Time of product return	10:32
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (22)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (23)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
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Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:26
----------------------	-------

Time of product return	11:35
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	_____
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (23)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (24)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
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Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:19
----------------------	-------

Time of product return	12:29
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (24)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (25)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
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Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:19
----------------------	-------

Time of product return	13:29
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (25)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (26)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
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Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:11
----------------------	-------

Time of product return	14:17
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (26)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (27)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:46
----------------------	-------

Time of product return	14:48
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	_____
-------------------------	-------

Tobacco plug vial number	_____
--------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	STICK NOT USED DUE TO CHARGER LOW ON BATTERY. PER SOURCE, VIAL # HAS BEEN CORRECTED.
---------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (27)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

Batch Number

B-08545

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (28)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:59
----------------------	-------

Time of product return	15:05
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (28)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (29)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:35
----------------------	-------

Time of product return	15:56
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (29)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (30)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
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Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:16
----------------------	-------

Time of product return	16:37
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (30)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (31)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	17:33
----------------------	-------

Time of product return	17:53
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

SODIM file number	
-------------------	--

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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PROD 04.000 (MAIN) RZ 02APR2015 (807)	1853 of 2382
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (31)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (32)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:54
----------------------	-------

Time of product return	18:00
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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PROD 04.000 (MAIN) RZ 02APR2015 (807)	1855 of 2382
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (32)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (33)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
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Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:23
----------------------	-------

Time of product return	18:49
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (33)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (34)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
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Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	19:47
----------------------	-------

Time of product return	19:58
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	19
--------------------------	----

SODIM file number	
-------------------	--

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (34)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (35)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
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Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	20:12
----------------------	-------

Time of product return	20:22
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	20
--------------------------	----

SODIM file number	
-------------------	--

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (35)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (36)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:36
----------------------	-------

Time of product return	20:49
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	21
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (36)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (37)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:32
----------------------	-------

Time of product return	22:01
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	22
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (37)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (38)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
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Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	22:03
----------------------	-------

Time of product return	22:17
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	23
--------------------------	----

SODIM file number	
-------------------	--

Comment	PER SOURCE, VIAL # HAS BEEN CORRECTED.
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (38)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (39)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	01 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:57
----------------------	-------

Time of product return	23:03
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	24
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (39)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (40)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:36
----------------------	-------

Time of product return	06:46
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (40)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (41)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:49
----------------------	-------

Time of product return	06:59
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (41)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (42)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	07:17
----------------------	-------

Time of product return	07:30
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	
-------------------	--

Comment	
---------	--

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (42)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (43)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
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Type of Product Use	THS 2.2 Menthol <input type="radio"/>
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If type of Product Use different from the randomization
please explain _____

Time of distribution	08:11
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Time of product return	08:21
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SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (43)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (44)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input checked="" type="radio"/>
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Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:22
----------------------	-------

Time of product return	08:30
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	_____
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (44)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (45)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:49
----------------------	-------

Time of product return	08:59
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (45)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (46)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:16
----------------------	-------

Time of product return	09:23
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (46)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (47)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:23
----------------------	-------

Time of product return	09:37
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (47)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Product Use

Form: Product administration-THS menthol (48)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	09:50
----------------------	-------

Time of product return	10:03
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	
-------------------	--

Comment	
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (48)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (49)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	10:22
----------------------	-------

Time of product return	10:35
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (49)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (50)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:03
----------------------	-------

Time of product return	11:09
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (50)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (51)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:22
----------------------	-------

Time of product return	11:31
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (51)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (52)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
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Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	11:36
----------------------	-------

Time of product return	11:42
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	
-------------------	--

Comment	
---------	--

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (52)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (53)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:19
----------------------	-------

Time of product return	13:27
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (53)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (54)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:41
----------------------	-------

Time of product return	13:49
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (54)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (55)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:29
----------------------	-------

Time of product return	16:37
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (55)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (56)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	16:37
----------------------	-------

Time of product return	16:49
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (56)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (57)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:11
----------------------	-------

Time of product return	17:20
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (57)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (58)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:25
----------------------	-------

Time of product return	17:33
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	19
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (58)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (59)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
------------------------------------	-------------

Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:05
----------------------	-------

Time of product return	18:13
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	20
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (59)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (60)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:50
----------------------	-------

Time of product return	19:19
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	21
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (60)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (61)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:47
----------------------	-------

Time of product return	19:54
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	22
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (61)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (62)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	20:26
----------------------	-------

Time of product return	20:34
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	23
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (62)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (63)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:10
----------------------	-------

Time of product return	22:17
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	24
--------------------------	----

SODIM file number	_____
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (63)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (64)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	22:17
----------------------	-------

Time of product return	22:27
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
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Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	25
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (64)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (65)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	02 MAR 2014
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Visit	Day 3 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:39
----------------------	-------

Time of product return	22:47
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	26
--------------------------	----

SODIM file number	_____
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (65)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (66)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:35
----------------------	-------

Time of product return	06:43
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	08DL0216COHG11016011
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (66)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (67)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:56
----------------------	-------

Time of product return	07:10
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	_____
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Comment	HST NOT STARTED
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (67)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (68)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:54
----------------------	-------

Time of product return	09:02
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	08DL0216COHG11016012
-------------------	----------------------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (68)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (69)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:03
----------------------	-------

Time of product return	09:12
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	08DL0216COHG11016013
-------------------	----------------------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (69)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (70)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:46
----------------------	-------

Time of product return	10:00
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	08DL0216COHG11016014
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (70)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (71)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:26
----------------------	-------

Time of product return	12:34
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	08DL0216COHG11016015
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (71)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (72)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:53
----------------------	-------

Time of product return	13:00
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	08DL0216COHG11016016
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (72)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (73)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:21
----------------------	-------

Time of product return	13:28
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	08DL0216COHG11016017
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (73)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (74)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:04
----------------------	-------

Time of product return	14:16
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	08DL0216COHG11016018
-------------------	----------------------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (74)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (75)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:17
----------------------	-------

Time of product return	15:24
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	08DL0216COHG11016019
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (75)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (76)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:25
----------------------	-------

Time of product return	15:35
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	08DL0216COHG11016020
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (76)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (77)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:45
----------------------	-------

Time of product return	15:53
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	08DL0216COHG11016021
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (77)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Product Use

Form: Product administration-THS menthol (78)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:35
----------------------	-------

Time of product return	16:43
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	08DL0216COHG11016022
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (78)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (79)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:47
----------------------	-------

Time of product return	17:57
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

SODIM file number	08DL0216COHG11016023
-------------------	----------------------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (79)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (80)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:37
----------------------	-------

Time of product return	18:46
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

SODIM file number	08DL0216COHG11016024
-------------------	----------------------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (80)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (81)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input type="radio"/>
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Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:58
----------------------	-------

Time of product return	19:09
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

SODIM file number	08DL0216COHG11016025
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (81)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (82)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:16
----------------------	-------

Time of product return	20:29
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

SODIM file number	08DL0216COHG11016026
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (82)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (83)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input type="radio"/>
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Type of Product Use	THS 2.2 Menthol <input type="radio"/>
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If type of Product Use different from the randomization
please explain _____

Time of distribution	20:59
----------------------	-------

Time of product return	21:12
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

SODIM file number	_____
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Comment	SMOKING EVENT NOT RECORDED
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (83)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (84)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:45
----------------------	-------

Time of product return	21:55
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	19
--------------------------	----

SODIM file number	08DL0216COHG11016027
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (84)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (85)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:27
----------------------	-------

Time of product return	22:37
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	20
--------------------------	----

SODIM file number	_____
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Comment	SMOKING EVENT NOT RECORDED
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Batch Number	B-08545
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PROD 04.000 (MAIN) RZ 02APR2015 (807)	1961 of 2382
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (85)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (86)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:37
----------------------	-------

Time of product return	22:45
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	21
--------------------------	----

SODIM file number	_____
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Comment	ILLOGICAL FILE #. HST DEVICE MALFUNCTIONED
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (86)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (87)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	03 MAR 2014
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Visit	Day 4 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:47
----------------------	-------

Time of product return	22:53
------------------------	-------

SODIM device number	216
---------------------	-----

SODIM sample holder number	1016
----------------------------	------

Tobacco plug kit number	T1580
-------------------------	-------

Tobacco plug vial number	22
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	ILLOGICAL FILE #. HST DEVICE MALFUNCTIONED
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (87)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (88)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
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Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:26
----------------------	-------

Time of product return	06:31
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	_____
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (88)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (89)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
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Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:52
----------------------	-------

Time of product return	07:08
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	_____
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (89)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (90)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:12
----------------------	-------

Time of product return	07:22
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	_____
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (90)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (91)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:30
----------------------	-------

Time of product return	07:37
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	_____
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (91)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (92)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
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If type of Product Use different from the randomization
please explain

Time of distribution	07:50
----------------------	-------

Time of product return	07:56
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1715
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Tobacco plug vial number	05
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (92)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (93)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:23
----------------------	-------

Time of product return	08:34
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	_____
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Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (93)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (94)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	08:56
----------------------	-------

Time of product return	09:03
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
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Tobacco plug kit number	T1715
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Tobacco plug vial number	07
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (94)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (95)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	10:19
----------------------	-------

Time of product return	10:24
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (95)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (96)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:51
----------------------	-------

Time of product return	10:56
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (96)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (97)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:27
----------------------	-------

Time of product return	11:33
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (97)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (98)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	12:13
----------------------	-------

Time of product return	12:20
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (98)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (99)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	12:50
----------------------	-------

Time of product return	12:55
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (99)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (100)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:14
----------------------	-------

Time of product return	13:19
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (100)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (101)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:45
----------------------	-------

Time of product return	13:51
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (101)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (102)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
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Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:52
----------------------	-------

Time of product return	14:58
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (102)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (103)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
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Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	16:20
----------------------	-------

Time of product return	16:27
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (103)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (104)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:52
----------------------	-------

Time of product return	16:59
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (104)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (105)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
------------------------------------	-------------

Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	17:47
----------------------	-------

Time of product return	17:57
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (105)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (106)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:52
----------------------	-------

Time of product return	19:00
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	19
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (106)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (107)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:28
----------------------	-------

Time of product return	19:34
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	20
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (107)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (108)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
------------------------------------	-------------

Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:19
----------------------	-------

Time of product return	20:29
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	21
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (108)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (109)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
------------------------------------	-------------

Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:55
----------------------	-------

Time of product return	21:02
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	22
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (109)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (110)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:06
----------------------	-------

Time of product return	22:10
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	23
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (110)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (111)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	22:13
----------------------	-------

Time of product return	22:18
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	24
--------------------------	----

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (111)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (112)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	04 MAR 2014
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Visit	Day 5 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:46
----------------------	-------

Time of product return	22:51
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	25
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (112)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (113)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	05 MAR 2014
------------------------------------	-------------

Visit	Day 6 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	10:09
----------------------	-------

Time of product return	10:15
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	<hr/>
-------------------------	-------

Tobacco plug vial number	<hr/>
--------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (113)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (114)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	05 MAR 2014
------------------------------------	-------------

Visit	Day 6 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:00
----------------------	-------

Time of product return	11:05
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	_____
-------------------------	-------

Tobacco plug vial number	_____
--------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (114)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (115)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	05 MAR 2014
------------------------------------	-------------

Visit	Day 6 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:19
----------------------	-------

Time of product return	11:24
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	_____
-------------------------	-------

Tobacco plug vial number	_____
--------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (115)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (116)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number	228
---------------------	-----

SODIM sample holder number	1029
----------------------------	------

Tobacco plug kit number	T1550
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	08DL0228COHG31029001
-------------------	----------------------

Comment

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (116)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (117)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	228
---------------------	-----

SODIM sample holder number	1029
----------------------------	------

Tobacco plug kit number	T1550
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	08DL0228COHG31029002
-------------------	----------------------

Comment	<hr/>
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (117)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (118)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	228
---------------------	-----

SODIM sample holder number	1029
----------------------------	------

Tobacco plug kit number	T1550
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	08DL0228COHG31029003
-------------------	----------------------

Comment	<hr/>
---------	-------

Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (118)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (119)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	228
---------------------	-----

SODIM sample holder number	1029
----------------------------	------

Tobacco plug kit number	T1550
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	08DL0228COHG31029004
-------------------	----------------------

Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (119)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (120)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	228
---------------------	-----

SODIM sample holder number	1029
----------------------------	------

Tobacco plug kit number	T1550
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	08DL0228COHG31029005
-------------------	----------------------

Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (120)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Product Use
Form: Product administration-THS menthol (121)
Data signed: (jeanellek1) 18 Jun 2015 14:53:18
Generated On: 20 Jul 2016 01:42:19

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	228
---------------------	-----

SODIM sample holder number	1029
----------------------------	------

Tobacco plug kit number	T1550
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	08DL0228COHG31029006
-------------------	----------------------

Comment	<hr/>
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Batch Number	B-08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product administration-THS menthol (121)

Data signed: (jeanellek1) 18 Jun 2015 14:53:18

Generated On: 20 Jul 2016 01:42:19

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: 2146

Folder: Product Use

Form: HST 4 hours (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:38

Generated On: 20 Jul 2016 01:42:19

Visit	Day 30 <input type="radio"/>
-------	------------------------------

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

If Not Done, please specify	<hr/>
-----------------------------	-------

Date DD/MMM/YYYY	29 MAR 2014
---------------------	-------------

SODIM device distribution time hour:min 24-hour clock	08:32
--	-------

SODIM device collection time hour:min 24-hour clock	12:03
--	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: HST 4 hours (2)

Data signed: (jeanellek1) 18 Jun 2015 14:53:38

Generated On: 20 Jul 2016 01:42:19

Visit	Day 60 <input type="radio"/>
-------	------------------------------

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

If Not Done, please specify

NO SMOKING EVENTS
DOCUMENTED FOR THIS
EVENT

Date
DD/MMM/YYYY

SODIM device distribution time
hour:min 24-hour clock

SODIM device collection time

hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: HST 4 hours (3)

Data signed: (jeanellek1) 18 Jun 2015 14:53:38

Generated On: 20 Jul 2016 01:42:19

Visit	Day 90 <input checked="" type="radio"/>
-------	---

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

If Not Done, please specify	SUBJECT DID NOT CHECK IN
-----------------------------	--------------------------

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

SODIM device distribution time hour:min 24-hour clock	
--	--

SODIM device collection time hour:min 24-hour clock	
--	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (1)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (2)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (3)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (4)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (5)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (6)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (7)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (8)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (9)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (10)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (11)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (12)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (13)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (20)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (23)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (25)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (26)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for mCC (27)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (1)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (4)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (8)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (12)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (15)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (16)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (17)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (18)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (19)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (20)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (21)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (22)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (23)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (24)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (25)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (26)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (27)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (28)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (29)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (30)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (31)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (32)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (33)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (34)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (35)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (36)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (37)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (38)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (39)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (40)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (41)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (42)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (43)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (44)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (45)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (46)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (47)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (48)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (49)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (50)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (51)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (52)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (53)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (54)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (55)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (56)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (57)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (58)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (59)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (60)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (61)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (62)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (63)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (64)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (65)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (67)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (83)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (85)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (86)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (87)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (88)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (89)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (90)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (91)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (92)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (93)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (94)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (95)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (96)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (97)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (98)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (99)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (100)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (101)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (102)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	
File Status	
Rejection / Error reason	
Date of analysis DD/MMM/YYYY	
Operator	
Comment	
Modified File Number	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (103)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (104)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (105)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (106)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (107)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (108)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (109)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (110)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (111)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (112)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (113)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (114)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (115)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	<hr/>
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File Status	<hr/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
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Operator	<hr/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (116)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	08DL0228COHG31029001
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	17 NOV 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (117)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	08DL0228COHG31029002
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	17 NOV 2014
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Operator	Anthony Bruchet <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (118)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	08DL0228COHG31029003
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	17 NOV 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (119)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	08DL0228COHG31029004
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	17 NOV 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (120)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	08DL0228COHG31029005
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	17 NOV 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Topography files status for THS menthol (121)
Generated On: 20 Jul 2016 01:42:19

SODIM file number	08DL0228COHG31029006
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	17 NOV 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (1)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1702_01_D1RV.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (2)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1702_02_GHE5.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (3)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1702_03_TQ0M.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (4)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
-------------	--

Picture File Name	T1702_04_XOJY.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (5)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1702_05_JGL0.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (6)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	06
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1702_06_31EA.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (7)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
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Tobacco plug vial number	07
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Level	0 
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Observation	<hr/>
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Picture File Name	T1702_07_1AON.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (8)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
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Tobacco plug vial number	08
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Level	0 
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Observation	<hr/>
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Picture File Name	T1702_08_B4HE.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (9)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	09
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1702_09_QGVG.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (10)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1702_10_E2HK.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (11)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1702_11_G36D.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (12)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1702_12_8B8C.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (13)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1702
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1702_13_M38G.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (1)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_01_DVT2.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (2)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_02_7Z15.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (3)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_03_20C7.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (4)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	04
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1578_04_1Y4H.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (5)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_05_OGNZ.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (6)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_06_DMOH.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (7)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	07
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_07_MKZG.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (8)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
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Tobacco plug vial number	08
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1578_08_BFPL.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (9)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1578_09_EWG4.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (10)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	10
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1578_10_4GYA.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (11)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
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Tobacco plug vial number	11
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_11_QNL1.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (12)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_12_LPMQ.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (13)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_13_UDSW.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (14)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	14
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_14_BLFF.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (15)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	15
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_15_7B7D.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (16)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	16
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1578_16_Z5GM.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (17)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	17
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1578_17_6CY7.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (18)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_18_190V.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (19)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	19
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_19_HUKF.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (20)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	20
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
-------------	--

Picture File Name	T1578_20_DKK9.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (21)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	21
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_21_RZN7.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (22)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	22
--------------------------	----

Level	NA 
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Observation	Not enough tobacco in the plug to perform the analysis 
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Picture File Name	T1578_22_IMCH.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (23)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	23
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_23_B68H.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (24)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1578
-------------------------	-------

Tobacco plug vial number	24
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1578_24_V9XU.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (1)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
-------------------------	-------

Tobacco plug vial number	01
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1608_01_7I65.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (2)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	02
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_02_5PW9.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (3)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	03
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1608_03_7G2Y.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (4)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	04
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_04_7XIB.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (5)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	05
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1608_05_PED0.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (6)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	06
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1608_06_ERAL.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (7)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	07
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_07_MSFS.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (8)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	08
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Level	0 <input type="radio"/>
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Observation	<hr/>
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Picture File Name	T1608_08_28W7.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (9)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	09
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1608_09_HEFN.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (10)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	10
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1608_10_68N9.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (11)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	11
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1608_11_BLCW.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (12)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	12
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_12_0EJV.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (13)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	13
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_13_4JZ9.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (14)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	14
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_14_BW55.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (15)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	15
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_15_J7HN.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (16)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	16
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_16_Z1V1.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (17)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	17
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Level	0 <input type="radio"/>
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Observation	<hr/>
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Picture File Name	T1608_17_YDBN.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (18)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	18
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_18_AVRT.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (19)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	19
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1608_19_7F9T.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (20)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	20
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1608_20_42JU.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (21)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	21
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_21_OUXP.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (22)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	22
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_22_FZRW.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (23)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	23
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_23_3R6E.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (24)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	24
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_24_Z4BL.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (25)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	25
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_25_2AW1.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (26)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1608
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Tobacco plug vial number	26
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1608_26_LIV9.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (1)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	01
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1580_01_Z7JT.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (2)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	02
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1580_02_UPZ0.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (3)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	03
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1580_03_VZDG.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (4)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	04
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1580_04_X0UQ.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (5)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	05
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_05_MQK0.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (6)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	06
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_06_TC8L.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (7)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	07
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_07_YNM2.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (8)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	08
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1580_08_AHSJ.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (9)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	09
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1580_09_D8VM.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (10)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	10
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1580_10_ZCSE.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (11)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	11
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_11_8PPZ.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (12)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	12
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_12_RUB5.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (13)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	13
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_13_Q0WL.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (14)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	14
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_14_IXLE.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (15)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	15
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_15_56OT.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (16)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	16
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1580_16_E6N7.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (17)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	17
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_17_1QQX.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (18)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	18
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_18_X19F.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (19)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	19
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1580_19_J4LY.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (20)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	20
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1580_20_FMSG.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (21)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	21
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1580_21_XFI0.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (22)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1580
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Tobacco plug vial number	22
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Level	0 <input type="radio"/>
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Observation	<hr/>
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Picture File Name	T1580_22_FLBZ.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (1)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	01
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1715_01_EDJQ.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (2)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	02
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_02_ZM55.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (3)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	03
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_03_206O.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (4)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	04
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1715_04_6X5Y.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (5)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	05
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1715_05_CAEA.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (6)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	06
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1715_06_7IN4.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (7)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	07
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_07_41FW.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (8)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	08
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1715_08_AFXK.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (9)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	09
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1715_09_VRYR.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (10)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	10
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1715_10_8IFF.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (11)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	11
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_11_FM90.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (12)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	12
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_12_DVIA.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (13)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	13
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_13_OCC9.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (14)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	14
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_14_4K86.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (15)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	15
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_15_G5YO.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (16)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	16
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_16_XKCU.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (17)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	17
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1715_17_9PYD.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (18)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	18
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_18_U1U6.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (19)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	19
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1715_19_GS4V.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (20)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
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Tobacco plug vial number	20
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_20_NC9B.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (21)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	21
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_21_CYHU.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (22)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	22
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_22_1U6V.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (23)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	23
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_23_FJY9.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (24)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	24
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_24_MJAD.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (25)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1715
-------------------------	-------

Tobacco plug vial number	25
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1715_25_RIJO.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (1)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	01
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1550_01_9ML6.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (2)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	02
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1550_02_XAT7.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (3)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	03
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1550_03_JAO7.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (4)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	04
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1550_04_QWCU.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (5)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	05
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1550_05_BUTS.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (6)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	06
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1550_06_GM8Q.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (7)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	07
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1550_07_HH25.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (8)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	08
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1550_08_HFHB.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (9)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	09
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1550_09_S6F5.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (10)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	10
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1550_10_OPLO.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
---------------------------------	-------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (11)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	11
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1550_11_SYFL.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (12)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	12
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1550_12_IVNC.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (13)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	13
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1550_13_LHG9.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (14)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	14
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1550_14_5VDJ.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (15)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	15
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1550_15_CGCQ.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (16)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	16
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1550_16_KSPV.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (17)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	17
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1550_17_7RCF.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (18)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	18
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1550_18_OS25.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (19)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
-------------------------	-------

Tobacco plug vial number	19
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1550_19_PXCJ.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Visual Inspection of the Tobacco Plugs Results for THS (20)
Generated On: 20 Jul 2016 01:42:19

Tobacco plug kit number	T1550
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Tobacco plug vial number	20
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1550_20_97XR.JPG
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Date of analysis DD/MMM/YYYY	19 JUN 2014
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Product Use

Form: Product use diary(Paper)

Data signed: (jeanellek1) 18 Jun 2015 14:53:38

Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used?

No ☒

Reason not done

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Product use diary(Paper) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

Was paper questionnaire used? No ☐

Reason not done _____

Date of completion
DD/MMM/YYYY _____

Time of completion
hh:mm _____

Date the questionnaire was completed for
DD/MMM/YYYY _____

What tobacco/nicotine product did you use today? _____

How many THS 2.2 tobacco sticks did you use today? _____

How many CC/ roll-your-own did you smoke today? _____

What NRT product did you used today? _____

How many times did you use an inhaler today? _____

How many times did you use a nasal spray today? _____

How many gums did you use today? _____

How many lozenges did you use today? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Product Use
Form: Product use diary(Paper) (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today? _____

How many times did you use other NRT products today
not listed previously? _____

What other tobacco product did you used today? _____

How many times did you use chewable/smokeless
tobacco today? _____

How many cigars/cigarillos did you smoke today? _____

How many times did you smoke a pipe today? _____

How many times did you use a tobacco product today
not listed previously? _____

How many times did you use an electronic cigarette
today? _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (jeanellek1) 18 Jun 2015 14:53:38

Generated On: 20 Jul 2016 01:42:19

Was there any Adverse Event for this subject?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

AE Identifier	1
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Adverse Event	HEADACHE
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Start Date	25 FEB 2014
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DD/MMM/YYYY

End Date	26 FEB 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input checked="" type="radio"/>
--------------------------	-------------------------------------

Severity	Mild Adverse Event <input checked="" type="radio"/>
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Serious AE	No <input checked="" type="radio"/>
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Seriousness Criteria	<hr/>
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Treatment given	No <input checked="" type="radio"/>
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AE related to Study Procedure	Not Related <input checked="" type="radio"/>
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Relationship to mCC/THS	Not Related <input checked="" type="radio"/>
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AE expectedness	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (jeanellek1) 18 Jun 2015 14:53:38

Generated On: 20 Jul 2016 01:42:19

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Previous and Concomitant Medication
Form: Previous and Concomitant Medication Y/N
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

Has the subject taken previous or concomitant
medication?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Device Events
Form: Device report - THS 2.2 menthol Cigarette Holder
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

Were there any events with the device?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Device Events
Form: Device report - THS 2.2 menthol Cigarette Holder (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Device Events
Form: Device report - THS 2.2 menthol Cigarette Holder (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Device Events
Form: Device report - THS 2.2 menthol Charging Unit
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

Were there any events with the device?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Device Events
Form: Device report - THS 2.2 menthol Charging Unit (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Device Events
Form: Device report - THS 2.2 menthol Charging Unit (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

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: 2146
Folder: Device Inventory
Form: Device Inventory - THS 2.2 menthol Cigarette Holder (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

Device Inventory	1
Log Number	

Date of Device Distribution	25 FEB 2014
DD/MMM/YYYY	

Time of	16:29
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1245496
----------------------	---------

Date of Device Collection	25 FEB 2014
DD/MMM/YYYY	

Time of	16:32
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Device Inventory
Form: Device Inventory - THS 2.2 menthol Cigarette Holder (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

Device Inventory	2
Log Number	

Date of Device Distribution	28 FEB 2014
DD/MMM/YYYY	

Time of	06:31
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1245496
----------------------	---------

Date of Device Collection	13 JUN 2014
DD/MMM/YYYY	

Time of	11:58
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Device Inventory
Form: Device Inventory - THS 2.2 menthol Cigarette Holder (3)
Data signed: (jeanellek1) 18 Jun 2015 14:53:38
Generated On: 20 Jul 2016 01:42:19

Device Inventory	3
Log Number	

Date of Device Distribution	28 FEB 2014
DD/MMM/YYYY	

Time of	06:31
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1308326
----------------------	---------

Date of Device Collection	13 JUN 2014
DD/MMM/YYYY	

Time of	11:58
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Device Inventory
Form: Device Inventory - THS 2.2 menthol Charging Unit (1)
Data signed: (jeanellek1) 18 Jun 2015 14:53:39
Generated On: 20 Jul 2016 01:42:19

Device Inventory	1
Log Number	

Date of Device Distribution	25 FEB 2014
DD/MMM/YYYY	

Time of	16:29
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
-------------	-----------------------

Device Serial Number	1318233
----------------------	---------

Date of Device Collection	25 FEB 2014
DD/MMM/YYYY	

Time of	16:32
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Folder: Device Inventory
Form: Device Inventory - THS 2.2 menthol Charging Unit (2)
Data signed: (jeanellek1) 18 Jun 2015 14:53:39
Generated On: 20 Jul 2016 01:42:19

Device Inventory	2
Log Number	

Date of Device Distribution	28 FEB 2014
DD/MMM/YYYY	

Time of	06:31
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
-------------	-----------------------

Device Serial Number	1318233
----------------------	---------

Date of Device Collection	13 JUN 2014
DD/MMM/YYYY	

Time of	11:58
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 06
Time of completion hh:mm	07:06
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 05
Assessment Status	Completed
What tobacco/nicotine product did you use today?	THS 2.2
How many THS 2.2 tobacco sticks did you use today?	19
How many CC/ roll-your-own did you smoke today?	-9
What NRT product did you used today?	Not Applicable
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (1)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 06
Time of completion hh:mm	19:43
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 06
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	13
How many CC/ roll-your-own did you smoke today?	2
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (2)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 07
Time of completion hh:mm	19:35
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 07
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	17
How many CC/ roll-your-own did you smoke today?	-9
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (3)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 08
Time of completion hh:mm	21:23
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 08
Assessment Status	Completed
What tobacco/nicotine product did you use today?	THS 2.2 and CC
How many THS 2.2 tobacco sticks did you use today?	13
How many CC/ roll-your-own did you smoke today?	9
What NRT product did you used today?	Not Applicable
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (4)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 09

Time of completion
hh:mm

21:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 09

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

THS 2.2 ☒

How many THS 2.2 tobacco sticks did you use today?

13

How many CC/ roll-your-own did you smoke today?

-9

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (5)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 MAR 10
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Time of completion hh:mm	20:37
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Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 10
---	-------------

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

What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
--	--

How many THS 2.2 tobacco sticks did you use today?	24
--	----

How many CC/ roll-your-own did you smoke today?	-9
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (6)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 11
Time of completion hh:mm	20:26
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 11
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	17
How many CC/ roll-your-own did you smoke today?	-9
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (7)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 12
Time of completion hh:mm	21:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 12
Assessment Status	Completed
What tobacco/nicotine product did you use today?	THS 2.2
How many THS 2.2 tobacco sticks did you use today?	14
How many CC/ roll-your-own did you smoke today?	-9
What NRT product did you used today?	Not Applicable
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (8)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 13
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 13
Assessment Status	Completed
What tobacco/nicotine product did you use today?	THS 2.2
How many THS 2.2 tobacco sticks did you use today?	20
How many CC/ roll-your-own did you smoke today?	-9
What NRT product did you used today?	Not Applicable
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (9)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 14
Time of completion hh:mm	20:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 14
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	11
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (10)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 15
Time of completion hh:mm	18:22
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 15
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	12
How many CC/ roll-your-own did you smoke today?	-9
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (11)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 16
Time of completion hh:mm	19:13
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 16
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	11
How many CC/ roll-your-own did you smoke today?	-9
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (12)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 17
Time of completion hh:mm	22:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 17
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	13
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (13)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 MAR 18
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Time of completion hh:mm	21:49
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Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 18
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Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	13
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (14)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 19
Time of completion hh:mm	21:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 19
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	12
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (15)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 20
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 20
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	12
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (16)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 MAR 21
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Time of completion hh:mm	19:12
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Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 21
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Assessment Status	Completed <input checked="" type="radio"/>
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What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	15
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (17)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (18)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 MAR 22
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Time of completion hh:mm	20:01
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Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 22
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Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
--	---

How many THS 2.2 tobacco sticks did you use today?	1
--	---

How many CC/ roll-your-own did you smoke today?	11
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (18)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (19)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 MAR 23
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Time of completion hh:mm	21:00
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Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 23
---	-------------

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

What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
--	---

How many THS 2.2 tobacco sticks did you use today?	8
--	---

How many CC/ roll-your-own did you smoke today?	6
---	---

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (19)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (20)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 MAR 24
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Time of completion hh:mm	23:01
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Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 24
---	-------------

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

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	9
---	---

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (20)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (21)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 MAR 25
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Time of completion hh:mm	20:00
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Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 25
---	-------------

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

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	12
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (21)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (22)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

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

Date of completion DD/MMM/YYYY	2014 MAR 27
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Time of completion hh:mm	09:16
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 26
---	-------------

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

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	11
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (22)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (23)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

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

Date of completion DD/MMM/YYYY	2014 MAR 28
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Time of completion hh:mm	21:01
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 28
---	-------------

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

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	11
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (23)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (24)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 30
Time of completion hh:mm	10:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 29
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	6
How many CC/ roll-your-own did you smoke today?	-9
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (24)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (25)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

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

Date of completion DD/MMM/YYYY	2014 MAR 31
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Time of completion hh:mm	11:00
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 30
---	-------------

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

What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
--	---

How many THS 2.2 tobacco sticks did you use today?	8
--	---

How many CC/ roll-your-own did you smoke today?	14
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (25)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (26)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 MAR 31
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Time of completion hh:mm	22:00
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Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 31
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Assessment Status	Completed <input checked="" type="radio"/>
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What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
--	--

How many THS 2.2 tobacco sticks did you use today?	10
--	----

How many CC/ roll-your-own did you smoke today?	-9
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (26)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (27)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

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

Date of completion DD/MMM/YYYY	2014 APR 01
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Time of completion hh:mm	19:10
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Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 01
---	-------------

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

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	11
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (27)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (28)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 APR 02
-----------------------------------	-------------

Time of completion hh:mm	20:07
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Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 02
---	-------------

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

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	13
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (28)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (29)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 APR 03
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Time of completion hh:mm	20:01
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Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 03
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Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

What tobacco/nicotine product did you use today?	Electronic cigarette <input checked="" type="radio"/>
--	---

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	-9
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (29)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	32
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (30)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 APR 04
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Time of completion hh:mm	20:02
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Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 04
---	-------------

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

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	7
---	---

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (30)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (31)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 APR 07
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Time of completion hh:mm	23:13
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 07
---	-------------

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

What tobacco/nicotine product did you use today?	Electronic cigarette <input checked="" type="radio"/>
--	---

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	-9
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (31)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	29
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (32)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 10
Time of completion hh:mm	19:13
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 10
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	10
How many CC/ roll-your-own did you smoke today?	6
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (32)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (33)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 APR 11
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Time of completion hh:mm	20:22
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 11
---	-------------

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

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	11
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (33)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (34)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 APR 12
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Time of completion hh:mm	21:00
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 12
---	-------------

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

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	12
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (34)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (35)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 APR 13
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Time of completion hh:mm	20:00
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 13
---	-------------

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

What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
--	--

How many THS 2.2 tobacco sticks did you use today?	9
--	---

How many CC/ roll-your-own did you smoke today?	-9
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (35)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (36)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 APR 15
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Time of completion hh:mm	09:01
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 14
---	-------------

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

What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
--	-------------------------------------

How many THS 2.2 tobacco sticks did you use today?	-9
--	----

How many CC/ roll-your-own did you smoke today?	10
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (36)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (37)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 16
Time of completion hh:mm	10:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 15
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	8
How many CC/ roll-your-own did you smoke today?	-9
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (37)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (38)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

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

Date of completion DD/MMM/YYYY	2014 APR 19
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Time of completion hh:mm	20:00
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 19
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Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
--	--

How many THS 2.2 tobacco sticks did you use today?	7
--	---

How many CC/ roll-your-own did you smoke today?	-9
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (38)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (39)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

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

Date of completion DD/MMM/YYYY	2014 APR 21
-----------------------------------	-------------

Time of completion hh:mm	22:15
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 21
---	-------------

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

What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
--	--

How many THS 2.2 tobacco sticks did you use today?	13
--	----

How many CC/ roll-your-own did you smoke today?	-9
---	----

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (39)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (40)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
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Date of completion DD/MMM/YYYY	2014 APR 22
-----------------------------------	-------------

Time of completion hh:mm	20:03
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Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 22
---	-------------

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

What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
--	---

How many THS 2.2 tobacco sticks did you use today?	5
--	---

How many CC/ roll-your-own did you smoke today?	3
---	---

What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
--------------------------------------	---

How many times did you use an inhaler today?	-9
--	----

How many times did you use a nasal spray today?	-9
---	----

How many gums did you use today?	-9
----------------------------------	----

How many lozenges did you use today?	-9
--------------------------------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (40)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	-9
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (41)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 23
Time of completion hh:mm	19:42
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 23
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2, CC, and Electronic Cigarette <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	4
How many CC/ roll-your-own did you smoke today?	5
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Product use diary (41)
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input checked="" type="radio"/>
--	---

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	27
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: End of study
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

End of study date	11 JUL 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:	Withdrawal by Subject <input checked="" type="radio"/>
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Details:	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Consent Withdrawal
Data signed: (jeanellek1) 18 Jun 2015 14:51:11
Generated On: 20 Jul 2016 01:42:19

Did the subject withdraw it's consent to the biobanking
for BoExp and risk markers?

No ☒

Date of withdrawal of consent for biobanking for BoEXP
and risk markers

Did the subject withdraw it's consent to the
transcriptomics analysis?

No ☒

Date of withdrawal of consent for transcriptomics
analysis

ZRHM-REXA-08-US: Covance Clinical Development Services, Dallas, Texas: 2146
Form: Withdrawal
Data signed: (jeanellek1) 18 Jun 2015 14:51:16
Generated On: 20 Jul 2016 01:42:19

Date of withdrawal	13 JUN 2014 DD/MMM/YYYY
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Did the subject withdraw it's consent from the main study?	Yes <input checked="" type="radio"/>
--	--------------------------------------

If available, please provide details	SUBJECT WITHDREW FROM THE STUDY DUE TO PERSONAL REASONS.
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Did the subject withdraw from the Protected Health Information (PHI)?	No <input type="radio"/>
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Did the subject confirm that samples collected up to the time of withdrawal can be analysed?	Yes <input checked="" type="radio"/>
--	--------------------------------------
