

Subject Case Report Forms

1235 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 21:53:10

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Form: Subject

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Screening number	1235
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

28 MAR 2014
DD/MMM/YYYY

Randomization Time

13:04
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Date of Visit

14 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

Yes ☒

Consent Date

14 MAR 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

14 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Inclusion Criterion Number	2
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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, Daytona Beach, Florida: 1235

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Inclusion Criterion Number

3

Inclusion Criterion

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

Result

Yes

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

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).
---------------------	---

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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

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

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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

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).
---------------------	---

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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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
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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, Daytona Beach, Florida: 1235

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

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

Result	No
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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, Daytona Beach, Florida: 1235

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

Exclusion Criterion Number

3

Exclusion Criterion

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

Result

No

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

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

Result	No <input checked="" type="radio"/>
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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, Daytona Beach, Florida: 1235

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

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

Result	No
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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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

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

Result	No
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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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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.
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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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

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, Daytona Beach, Florida: 1235

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

Exclusion Criterion Number	10
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Exclusion Criterion	The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or NRT), as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

Exclusion Criterion Number	12
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Exclusion Criterion	If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

Exclusion Criterion	The subject has a positive urine drug test. <input checked="" type="radio"/>
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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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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.	<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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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"/>
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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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

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

Result	No <input checked="" type="radio"/>
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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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

Exclusion Criterion Number	21
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Exclusion Criterion	For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.
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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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Sex	Male
Race	White
Other, specify	
Ethnicity	Hispanic
Date the Subject signed the Informed Consent	14 MAR 2014 DD/MMM/YYYY
Time the Subject signed the Informed Consent	09:29 hour:min 24-hour clock
Age(Derived)	24

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Date of collection

14 MAR 2014
DD/MMM/YYYY

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

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Date of collection

14 MAR 2014
DD/MMM/YYYY

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

No ☒

Number

Diagnosis Description

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

Yes ☒

Date of assessment

14 MAR 2014
DD/MMM/YYYY

Time of assessment

10:29
hour:min 24-hour clock

Pulse rate

57
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

114
mmHg

Blood Pressure (diastolic)

68
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

14 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 14 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

14 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 EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

14 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 EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

14 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 EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

14 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 EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

14 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 EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Date

14 MAR 2014
DD/MMM/YYYY

Brand name

NEWPORT 100'S

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Has the subject seen a THS 2.2 menthol product
demonstration?

Yes ☒

If the subject did not see the demonstration please
explain

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Date of Assessment

14 MAR 2014
DD/MMM/YYYY

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

No ☐

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

Yes ☐

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

>19 ☐

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

Yes ☐

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

No ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

14 MAR 2014
DD/MMM/YYYY

Weight

62.6
kg

Height

177.8
cm

BMI (Derived)

19.8
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 14 MAR 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 54
beats per minute

QRS Interval 96
msec

QT Interval 431
msec

QTcB Interval 409
msec

QTcF Interval 416
msec

PR Interval 175
msec

Interpretation Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 19:04:43

Generated On: 20 Jul 2016 21:53:10

If Abnormal, Clinical Significance _____

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

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 14 MAR 2014
DD/MMM/YYYY

Time of assessment 10:59

Predicted FVC value 5.57
L

Best measured FVC value 6.28
L

Percent of predicted FVC value 113
%

Best measured FEV1 value 4.58
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Predicted FEV1 value	4.61 L
----------------------	-----------

Percent of predicted FEV1 value	99 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	0.73
-----------------------------------	------

MEF 25/75 value	3.45 L/s
-----------------	-------------

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

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 14 MAR 2014

Time of assessment 11:39

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 5.57 L

Best measured FVC value 5.87 L

Percent of predicted FVC value 105 %

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Best measured FEV1 value	4.65 L
Predicted FEV1 value	4.61 L
Percent of predicted FEV1 value	101 %
Calculated ratio between FEV1/FVC	0.79
MEF 25/75 value	4.32 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, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

21 MAR 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

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

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

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

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date of sample collection	14 MAR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	10:15 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 14 MAR 2014
DD/MMM/YYYY

Time of assessment 10:19
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 29 Mar 2015 19:04:44

Generated On: 20 Jul 2016 21:53:10

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	14 MAR 2014 DD/MMM/YYYY
---------------------------	----------------------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

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

Date of Sample Collection YYYY/MM/DD	14 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	11:12
---------------------------	-------

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

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

Result	90
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

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

Date of Sample Collection YYYY/MM/DD	14 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	11:12
---------------------------	-------

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

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

Result	13
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

CHOLESTEROL, TOTAL

Code

001065

Result

119

Unit

MG/DL

Lower limit

100

Upper limit

189

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

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

Date of Sample Collection YYYY/MM/DD	14 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	11:12
---------------------------	-------

Analyte Name	PROTEIN, TOTAL, SERUM
--------------	-----------------------

Code	001073
------	--------

Result	7.0
--------	-----

Unit	G/DL
------	------

Lower limit	6.0
-------------	-----

Upper limit	8.5
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

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

Date of Sample Collection YYYY/MM/DD	14 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	11:12
---------------------------	-------

Analyte Name	ALBUMIN, SERUM
--------------	----------------

Code	001081
------	--------

Result	4.6
--------	-----

Unit	G/DL
------	------

Lower limit	3.5
-------------	-----

Upper limit	5.5
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

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

Date of Sample Collection YYYY/MM/DD	14 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	11:12
---------------------------	-------

Analyte Name	BILIRUBIN, TOTAL
--------------	------------------

Code	001099
------	--------

Result	0.4
--------	-----

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

Lower limit	0.0
-------------	-----

Upper limit	1.2
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

ALKALINE PHOSPHATASE, S

Code

001107

Result

57

Unit

IU/L

Lower limit

39

Upper limit

117

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	LDH
Code	001115
Result	179
Unit	IU/L
Lower limit	0
Upper limit	225
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:12

Analyte Name

AST (SGOT)

Code

001123

Result

15

Unit

IU/L

Lower limit

0

Upper limit

40

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

TRIGLYCERIDES

Code

001172

Result

68

Unit

MG/DL

Lower limit

0

Upper limit

114

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	POTASSIUM, SERUM
Code	001180
Result	5.3
Unit	MMOL/L
Lower limit	3.5
Upper limit	5.2
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

SODIUM, SERUM

Code

001198

Result

139

Unit

MMOL/L

Lower limit

134

Upper limit

144

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

BILIRUBIN, DIRECT

Code

001222

Result

0.10

Unit

MG/DL

Lower limit

0.00

Upper limit

0.40

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

CREATININE, SERUM

Code

001370

Result

0.89

Unit

MG/DL

Lower limit

0.76

Upper limit

1.27

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:12

Analyte Name

ALT (SGPT)

Code

001545

Result

13

Unit

IU/L

Lower limit

0

Upper limit

44

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	GGT
Code	001958
Result	10
Unit	IU/L
Lower limit	0
Upper limit	65
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

HEP C VIRUS AB

Code

140683

Result

<0.1

Unit

S/CO RATIO

Lower limit

0.0

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:49

Generated On: 20 Jul 2016 21:53:10

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:49

Generated On: 20 Jul 2016 21:53:10

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

HIV 1/O/2 ABS, QUAL

Code

001725

Result

NON REACTIVE

Unit

Lower limit

NON REACTIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:49

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:49

Generated On: 20 Jul 2016 21:53:10

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

HBSAG SCREEN

Code

006510

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:49

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:49

Generated On: 20 Jul 2016 21:53:10

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

HIV 1/O/2 ABS-INDEX VALUE

Code

150010

Result

<1.00

Unit

Lower limit

<1.00

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:49

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

WBC

Code

005025

Result

8.5

Unit

X10E3/UL

Lower limit

3.4

Upper limit

10.8

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	RBC
Code	005033
Result	4.81
Unit	X10E6/UL
Lower limit	4.14
Upper limit	5.80
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	HEMOGLOBIN
Code	005041
Result	14.4
Unit	G/DL
Lower limit	12.6
Upper limit	17.7
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	HEMATOCRIT
Code	005058
Result	42.0
Unit	%
Lower limit	37.5
Upper limit	51.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

MCV

Code

015065

Result

87

Unit

FL

Lower limit

79

Upper limit

97

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	MCH
Code	015073
Result	29.9
Unit	PG
Lower limit	26.6
Upper limit	33.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

MCHC

Code

015081

Result

34.3

Unit

G/DL

Lower limit

31.5

Upper limit

35.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	NEUTROPHILS
Code	015107
Result	49
Unit	%
Lower limit	40
Upper limit	74
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

LYMPHS

Code

015123

Result

35

Unit

%

Lower limit

14

Upper limit

46

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	MONOCYTES
Code	015131
Result	7
Unit	%
Lower limit	4
Upper limit	12
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	EOS
Code	015149
Result	8
Unit	%
Lower limit	0
Upper limit	5
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	BASOS
Code	015156
Result	1
Unit	%
Lower limit	0
Upper limit	3
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

PLATELETS

Code

015172

Result

231

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

NEUTROPHILS (ABSOLUTE)

Code

015909

Result

4.2

Unit

X10E3/UL

Lower limit

1.4

Upper limit

7.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	LYMPHS (ABSOLUTE)
Code	015917
Result	3.0
Unit	X10E3/UL
Lower limit	0.7
Upper limit	3.1
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	MONOCYTES(ABSOLUTE)
Code	015925
Result	0.6
Unit	X10E3/UL
Lower limit	0.1
Upper limit	0.9
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:12

Analyte Name

EOS (ABSOLUTE)

Code

015933

Result

0.7

Unit

X10E3/UL

Lower limit

0.0

Upper limit

0.4

Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	14 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:12
Analyte Name	BASO (ABSOLUTE)
Code	015941
Result	0.0
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.2
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 29 Mar 2015 19:04:50

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

07357100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:38

Analyte Name

SPECIFIC GRAVITY

Code

13060

Result

1.01

Unit

Lower limit

1.001

Upper limit

1.035

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(14 MAR 2014)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:38

Analyte Name

PH

Code

13078

Result

6

Unit

Lower limit

5

Upper limit

8

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

10:38

Analyte Name

GLUCOSE

Code

13086

Result

NORMAL

Unit

Lower limit

NORMAL

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

10:38

Analyte Name

PROTEIN

Code

13094

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:38

Analyte Name

OCCULT BLOOD

Code

13102

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:38

Analyte Name

BILIRUBIN

Code

13104

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

14 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:38

Analyte Name

NITRITE, URINE

Code

13106

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Screening

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:48

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 14 MAR 2014
DD/MMM/YYYY

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

Date of Visit

26 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Inclusion Criterion Number

3

Inclusion Criterion

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

Result

Yes

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Exclusion Criterion Number

3

Exclusion Criterion

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

Result

No

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.	<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, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 12:58
hour:min 24-hour clock

Pulse rate 52
beats per minute

Respiratory rate 12
breaths per minute

Blood Pressure (systolic) 111
mmHg

Blood Pressure (diastolic) 69
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

Which Product Arm would you prefer to be randomized
to:

THS 2.2 menthol ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

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

Outcome ☒ Normal

Abnormal, please specify _____

Clinically significant _____

Not Done ☐ False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Back ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hcoleman1) 18 Jun 2015 21:18:36

Generated On: 20 Jul 2016 21:53:10

Brand name

NEWPORT 100'S GREEN

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

Was the THS 2.2 menthol product trial performed?

Yes ☒

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

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

1

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

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

12:36
hour:min 24-hour clock

Weight

63.1
kg

Waist circumference

80
cm

BMI

20.0

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Time of sample collection	12:33 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, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 12:42
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 29 Mar 2015 19:04:51

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	12:44
	hour:min 24-hour clock

Result	23
	ppm

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Admission (Day -2)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 26 MAR 2014
DD/MMM/YYYY

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Date of Visit

27 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

09:14
hour:min 24-hour clock

Pulse rate

68
beats per minute

Respiratory rate

18
breaths per minute

Blood Pressure (systolic)

120
mmHg

Blood Pressure (diastolic)

60
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:12
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

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)	15
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

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	12:03
---	-------

Result(ppm)	31
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

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	16:16
---	-------

Result(ppm)	32
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:52

Generated On: 20 Jul 2016 21:53:10

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	20:04
---	-------

Result(ppm)	40
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Start Time	10:07
	hour:min 24-hour clock

End Time	14:04
	hour:min 24-hour clock

Volume	647
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Were samples for 4h collected? Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected? 13

How many back up tubes were collected? 13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004049
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	9.20
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	.
----------------	---

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	20
---------------------------	----

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

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment

2014 MAR 27

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:16
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Extremely ☒

2. Did cigarettes taste good?

Extremely ☒

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

Extremely ☒

4. Did smoking calm you down?

Extremely ☒

5. Did smoking make you feel more awake?

Extremely ☒

6. Did smoking make you feel less irritable?

Extremely ☒

7. Did smoking help you concentrate?

Extremely ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

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? Extremely ☐

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:11 hour:min 24-hour clock
--------------------	---------------------------------

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

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

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?	No <input type="radio"/>
--	--------------------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

Not at all ☐

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:14 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years 00 Years

Months 00 Months

Days 00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? NEWPORT 100'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:14 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

Currently (last 3 months) ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:14 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

1 year ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:14 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

5 years ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:14 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:14 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

15 years ago ☒

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

None ☒

Manufactured Cigarettes
per day

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:14 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?	18 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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years 00 Years

Months 00 Months

Days 00 Days

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

Time 20 years ago ☒

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

Manufactured Cigarettes
per day

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

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	27 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:14 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?	18 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, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Months _____

Days _____

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years _____ 00 Years

Months _____ 00 Months

Days _____ 00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? NEWPORT 100'S

Time _____ More than 20 years ago ☒

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

Manufactured Cigarettes
per day _____

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

Hand-rolled Cigarettes
per day _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Supplemental Questions

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

27 MAR 2014
DD/MMM/YYYY

Time of assessment

21:15

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

03 minutes

Comments (open-end)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:15

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:15

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:15

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:15

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:15

1. How long it takes for the subject to complete the SQ 03 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:53

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 MAR 2014
DD/MMM/YYYY

Time of assessment 21:15

1. How long it takes for the subject to complete the SQ 03 minutes

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Type	QSU
------	-----

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

Date of assessment	2014 MAR 27
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:15
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Strongly agree <input checked="" type="radio"/>
---	---

3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Do not agree or disagree <input checked="" type="radio"/>
---	---

5. All I want right now is a cigarette	Strongly agree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

9. Smoking would make me less depressed Strongly agree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002662
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Analyte	HPMA
---------	------

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

Result	636
--------	-----

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

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002662
----------------	----------------

Analyte	CEMA
---------	------

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

Result	72.9
--------	------

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

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002662
----------------	----------------

Analyte	HBMA
---------	------

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

Result	267
--------	-----

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

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003175
----------------	----------------

Analyte	NNAL
---------	------

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

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-MAR-27
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003175
----------------	----------------

Analyte	NNN
---------	-----

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

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-04
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Date of Collection	2014-MAR-27
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112470001587
Analyte	HEMA
Sample type	URINE
Result	2.07
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-27
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001134
Analyte	COT
Sample type	URINE
Result	1820
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001134
Analyte	COT-GLUC
Sample type	URINE
Result	2890
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001134
Analyte	NIC
Sample type	URINE
Result	532
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001134
Analyte	NIC-GLUC
Sample type	URINE
Result	429
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001134
Analyte	THCOT
Sample type	URINE
Result	2660
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001134
Analyte	THCOT-GLUC
Sample type	URINE
Result	1750
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112490001587
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-07
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Date of Collection	2014-MAR-27
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001609
Analyte	1-NA
Sample type	URINE
Result	67.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-27
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001609
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Analyte	2-NA
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Sample type	URINE
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Result	20.6
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-09
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Date of Collection	2014-MAR-27
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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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001609
Analyte	4-ABP
Sample type	URINE
Result	16.7
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-27
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001609
Analyte	O-TOL
Sample type	URINE
Result	124
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-27
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112530000505
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Analyte	11-DTXB2
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-11
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Date of Collection	2014-MAR-27
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112540000498
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Analyte	IPF2A-III
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Sample type	URINE
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Result	140
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-12
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Date of Collection	2014-MAR-27
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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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115190003611
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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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	AA99598-03
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Date of Collection	2014-MAR-27
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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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003609
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Analyte	SBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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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	AA99598-01
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Date of Collection	2014-MAR-27
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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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003609
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Analyte	SPMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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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	AA99598-01
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Date of Collection	2014-MAR-27
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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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115180003611
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Analyte	MHBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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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	
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Celerion Study Number	AA99598-02
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Date of Collection	2014-MAR-27
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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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:54

Generated On: 20 Jul 2016 21:53:10

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115160001587
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Analyte	CREATININE
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Sample type	URINE
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Result	.
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Result Unit	MG/DL
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-14
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Date of Collection	2014-MAR-27
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Date of Visit

28 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Randomization number (4 digits)	2018
---------------------------------	------

Allocation Arm	mCC <input checked="" type="radio"/>
----------------	--------------------------------------

Cigarette Consumption	Greater than 19 conventional menthol cigarettes per day <input checked="" type="radio"/>
-----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 08:52
hour:min 24-hour clock

Pulse rate 67
beats per minute

Respiratory rate 18
breaths per minute

Blood Pressure (systolic) 116
mmHg

Blood Pressure (diastolic) 69
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Was the Gas Transfer performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 05:52

DLCO value 21.55
ml/min/mmHg

KCO value 0.93
mmol/min/kPa/L

DLCO/VA value 2.79
mL/min/mmHg/L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 06:14

VC value 6.35
L

TLC value 4.75
L

IC value 0.48
L

FRC value 4.27
L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:18:36

Generated On: 20 Jul 2016 21:53:10

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

06:40

Name of bronchodilator

ALBUTEROL SULFATE

Dose

180 MCG

Predicted FVC value

5.56
L

Best measured FVC value

6.35
L

Percent of predicted FVC value

114
%

Best measured FEV1 value

4.68
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:18:36

Generated On: 20 Jul 2016 21:53:10

Predicted FEV1 value	4.59 L
----------------------	-----------

Percent of predicted FEV1 value	101 %
---------------------------------	----------

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

MEF 25/75 value	3.68 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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

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

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

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

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	05:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?	Yes <input checked="" type="radio"/>
--	--------------------------------------

Date DD/MMM/YYYY	28 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	05:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

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	07:19
---	-------

Result(ppm)	33
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	12:06
---	-------

Result(ppm)	25
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

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)	30
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:55

Generated On: 20 Jul 2016 21:53:10

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	20:02
---	-------

Result(ppm)	47
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

28 MAR 2014

05:30

trans-3'-hydroxyc
otinine

28 MAR 2014

05:30

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Time of caffeine tablet intake	10:54
	hour:min 24-hour clock

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

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
28 MAR 2014	16:49	Caffeine
28 MAR 2014	16:49	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	05:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Start Date	28 MAR 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	06:28 hour:min 24-hour clock
------------	---------------------------------

End Date	29 MAR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	06:04 hour:min 24-hour clock
----------	---------------------------------

Volume	2668 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Were samples for 24h collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

14

How many back up tubes were collected?

13

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 28
DD/MMM/YYYY

Time of assessment

06:30
hour:min 24-hour clock

Assessment Status

Completed ☒

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

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Severe ☐

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 28
DD/MMM/YYYY

Time of assessment

06:29
hour:min 24-hour clock

Assessment Status

Completed ☒

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

No ☒

If YES, please answer the following questions:

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

-9

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

Not Applicable ☒

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

Not Applicable ☒

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

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

05:30
hour:min 24-hour clock

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

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

Yes ☒

Time of Sample Collection

05:30
hour:min 24-hour clock

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

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

Yes ☒

Time of Buccal Collection

16:06
hour:min 24-hour clock

Time of Nasal Epithelial Collection

16:04
hour:min 24-hour clock

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	174
Reported Numeric Result	174
Reference Range low	44
Reference Range high	249
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
--------------	-----------------

Lab Test ID	RCT142
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	89
Reported Numeric Result	89
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	143
Reported Numeric Result	143
Reference Range low	128
Reference Range high	236
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
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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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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.1
Reported Numeric Result	7.1
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.1
Reported Numeric Result	4.1
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	58
Reported Numeric Result	58
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	156
Reported Numeric Result	156
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	142
Reported Numeric Result	142
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	W098741
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	10
Reported Numeric Result	10
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	CREATININE (RATE BLANKED)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	2.3
Reported Numeric Result	2.3
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High Telephone ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	12
Reported Numeric Result	12
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT6
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	18
Reported Numeric Result	18
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.67
Reported Numeric Result	0.67
Reference Range low	0.12
Reference Range high	0.92
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:30
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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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	29
Reported Numeric Result	29
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:30
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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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
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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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.74
Reported Numeric Result	0.74
Reference Range low	0.00
Reference Range high	0.57
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.07
Reported Numeric Result	0.07
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
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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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	207
Reported Numeric Result	207
Reference Range low	140
Reference Range high	400
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:30
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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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	57.0
Reported Numeric Result	57.0
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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:30
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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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	30.2
Reported Numeric Result	30.2
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:30
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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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	5.8
Reported Numeric Result	5.8
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:30
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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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	6.4
Reported Numeric Result	6.4
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:30
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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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.6
Reported Numeric Result	0.6
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	W098741
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:30
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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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	41
Reported Numeric Result	41
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
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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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.7
Reported Numeric Result	4.7
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (43)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
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Actual Collection Time	05:30
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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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (43)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	87
Reported Numeric Result	87
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (43)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (44)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
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Actual Collection Date	2014 03 28
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Actual Collection Time	05:30
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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, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (44)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13.6
Reported Numeric Result	13.6
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (44)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (45)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT7
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (45)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	11.56
Reported Numeric Result	11.56
Reference Range low	3.80
Reference Range high	10.70
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (45)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (46)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT71
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (46)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

RBC MORPHOLOGY 1

Test ID

Test Status

Done 

Reported Text Result

NORMOCYTIC

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (46)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (47)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT8
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (47)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.59
Reported Numeric Result	6.59
Reference Range low	1.96
Reference Range high	7.23
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (47)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (48)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT9
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (48)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.49
Reported Numeric Result	3.49
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, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (48)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (49)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (49)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR NITRITE

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (49)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (50)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (50)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.019
Reported Numeric Result	1.019
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (50)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (51)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (51)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (51)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (52)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (52)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (52)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (53)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (53)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (53)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (54)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (54)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR GLUCOSE

Test ID

Test Status

Done 

Reported Text Result

NORMAL

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (54)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (55)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

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	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (55)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR BILIRUBIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (55)

Data signed: (hfarmer1) 29 Mar 2015 19:04:59

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCRL
--------------	---------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	9.46
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	24(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	24RHCRL
--------------	---------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	6.56
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	25-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	25HCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	4.70
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	27-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	27HCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	11.60
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	4B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	4BHCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	10.66
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	5A,6A-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5A6AECNL
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.46
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	5B,6B-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5B6BECNL
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	26.83
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	6A-HYDROXY-5A-CHOLESTAN OL
---------	-------------------------------

Analyte code	6AH5ACNL
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	13.70
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	7-KETOCHOLESTEROL
---------	-------------------

Analyte code	7KCRL
--------------	-------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	15.43
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	7A-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7AHCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	13.46
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	7B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7BHCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.86
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3209874139
-------------------------	------------

Analyte	CHOLESTEROL
---------	-------------

Analyte code	CHOL
--------------	------

Result	
--------	--

Result Unit	MG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	0.50
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004050
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	6.00
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-MAR-28
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004051
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	9.70
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-28
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment

2014 MAR 28

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:05

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Extremely ☒

2. Did cigarettes taste good?

Extremely ☒

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

Extremely ☒

4. Did smoking calm you down?

Extremely ☒

5. Did smoking make you feel more awake?

Not at all ☒

6. Did smoking make you feel less irritable?

Not at all ☒

7. Did smoking help you concentrate?

Not at all ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

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? Extremely ☐

12. Did you enjoy smoking? Extremely ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	28 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:13 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Strongly agree <input type="radio"/>
--	--------------------------------------

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Strongly agree <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"/>
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:04:56

Generated On: 20 Jul 2016 21:53:10

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Strongly agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Agree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 MAR 28
DD/MMM/YYYY	
Time of assessment	20:05
hour:min 24-hour clock	
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Strongly agree <input checked="" type="radio"/>
3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
4. I could control things better right now if I could smoke	Strongly agree <input checked="" type="radio"/>
5. All I want right now is a cigarette	Strongly agree <input checked="" type="radio"/>
6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

7. A cigarette would taste good now Strongly agree ☐

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 Strongly agree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done 

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	42
Reported Numeric Result	42
Reference Range low	30
Reference Range high	63
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	C-REACTIVE PROTEIN (N HS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.132
Reported Numeric Result	0.132
Reference Range low	
Reference Range high	<=0.287
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	APOLIPOPROTEIN A1, RAND
---------------	-------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	109
----------------------	-----

Reported Numeric Result	109
-------------------------	-----

Reference Range low	110
---------------------	-----

Reference Range high	205
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Low 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input type="radio"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	311
Reported Numeric Result	311
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	9.68
Reported Numeric Result	9.68
Reference Range low	3.70
Reference Range high	13.90
Range Units	UMOL/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	296.8
Reported Numeric Result	296.8
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098741
--------------	---------

Actual Collection Date	2014 03 28
------------------------	------------

Actual Collection Time	05:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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Test ID	<hr/>
---------	-------

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	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:57

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002673
Analyte	HPMA
Sample type	URINE
Result	809
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002673
Analyte	CEMA
Sample type	URINE
Result	106
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002673
Analyte	HBMA
Sample type	URINE
Result	392
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003204
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-04
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Date of Collection	2014-MAR-28
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003204
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Analyte	NNN
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112470001598
Analyte	HEMA
Sample type	URINE
Result	2.85
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:11

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001136
Analyte	COT
Sample type	URINE
Result	1810
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-29
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001136
Analyte	COT-GLUC
Sample type	URINE
Result	5050
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-29
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001136
Analyte	NIC
Sample type	URINE
Result	813
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-29
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
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Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001136
Analyte	NIC-GLUC
Sample type	URINE
Result	898
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-29
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001136
Analyte	THCOT
Sample type	URINE
Result	2810
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-29
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001136
Analyte	THCOT-GLUC
Sample type	URINE
Result	2380
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-29
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112490001598
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
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Celerion Study Number	AA99128-07
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Date of Collection	2014-MAR-28
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112500000436
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	1510
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Result Unit	NG/ML
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Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-08
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Date of Collection	2014-MAR-28
--------------------	-------------

Timepoint-minutes	0
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 21:53:10

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112500000436
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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Result	1740
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

Timepoint-minutes	0
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 21:53:10

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001620
Analyte	1-NA
Sample type	URINE
Result	66.7
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001620
Analyte	2-NA
Sample type	URINE
Result	22.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001620
Analyte	4-ABP
Sample type	URINE
Result	15.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001620
Analyte	O-TOL
Sample type	URINE
Result	133
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112530000507
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Analyte	11-DTXB2
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-11
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Date of Collection	2014-MAR-28
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
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Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112540000500
Analyte	IPF2A-III
Sample type	URINE
Result	218
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-12
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05113320000217
Analyte	AMES
Sample type	URINE
Result	26.3
Result Unit	REV/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-15
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115190003622
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003613
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Analyte	SBMA
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Sample type	URINE
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Result	.
--------	---

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

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003613
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115180003622
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	.
--------	---

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

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:12

Generated On: 20 Jul 2016 21:53:10

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115160001598
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Analyte	CREATININE
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Sample type	URINE
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Result	.
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Result Unit	MG/DL
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	0
-----------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001958
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	408
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 21:53:10

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001958
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	43.3
--------	------

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

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 21:53:10

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112520000436
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	504
--------	-----

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

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 21:53:10

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112520000436
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Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	128
--------	-----

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

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-MAR-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 21:53:10

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Date of Visit

29 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

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

10:45
hour:min 24-hour clock

Pulse rate

87
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

111
mmHg

Blood Pressure (diastolic)

65
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	29 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	29 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	29 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: CO Breath Test (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

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	06:48
---	-------

Result(ppm)	18
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: CO Breath Test (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

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	12:01
---	-------

Result(ppm)	39
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: CO Breath Test (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

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	16:01
---	-------

Result(ppm)	40
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: CO Breath Test (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

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	20:02
---	-------

Result(ppm)	35
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: 24 hour urine collections

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Start Time	06:04
	hour:min 24-hour clock

End Date	30 MAR 2014
	DD/MMM/YYYY

End Time	06:17
	hour:min 24-hour clock

Volume	1699
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Sample Urine Collection

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 29
DD/MMM/YYYY

Time of assessment

06:31
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?

None ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 1

Form: Cough Assessment

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 29
DD/MMM/YYYY

Time of assessment

06:29
hour:min 24-hour clock

Assessment Status

Completed ☒

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

No ☒

If YES, please answer the following questions:

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

-9

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

Not Applicable ☒

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

Not Applicable ☒

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

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004052
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Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
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Result	8.60
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Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	.
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Detection method	SPECTROPHOTOMETRIC
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Lower limit of quantification	0.500
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Planned time point (Hour)	20
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Day of Visit	1
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Celerion Study Number	AA99128-16
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Date of Collection	2014-MAR-29
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment

2014 MAR 29

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:08

hour:min 24-hour clock

Assessment Status

Completed ☐

1. Was smoking satisfying?

Extremely ☐

2. Did cigarettes taste good?

Extremely ☐

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

Extremely ☐

4. Did smoking calm you down?

Extremely ☐

5. Did smoking make you feel more awake?

Extremely ☐

6. Did smoking make you feel less irritable?

Extremely ☐

7. Did smoking help you concentrate?

Extremely ☐

8. Did smoking reduce your hunger for food?

Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:13

Generated On: 20 Jul 2016 21:53:10

9. Did smoking make you dizzy? Very little ☐

10. Did smoking make you nauseous? Little ☐

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

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Type	QSU
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Date of Birth	(b) (6)
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Date of assessment	2014 MAR 29
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DD/MMM/YYYY

Time of assessment	20:02
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hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Strongly agree <input checked="" type="radio"/>
--	---

3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Do not agree or disagree <input checked="" type="radio"/>
---	---

5. All I want right now is a cigarette	Strongly agree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

7. A cigarette would taste good now Strongly agree ☐

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 Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002674
Analyte	HPMA
Sample type	URINE
Result	1450
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002674
Analyte	CEMA
Sample type	URINE
Result	194
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002674
Analyte	HBMA
Sample type	URINE
Result	659
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003205
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-04
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Date of Collection	2014-MAR-29
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003205
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Analyte	NNN
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Sample type	URINE
-------------	-------

Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-MAR-29
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112470001599
Analyte	HEMA
Sample type	URINE
Result	4.50
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001137
Analyte	COT
Sample type	URINE
Result	2320
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001137
Analyte	COT-GLUC
Sample type	URINE
Result	8750
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001137
Analyte	NIC
Sample type	URINE
Result	525
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	1
-----------------	---

Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001137
Analyte	NIC-GLUC
Sample type	URINE
Result	1180
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001137
Analyte	THCOT
Sample type	URINE
Result	6210
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001137
Analyte	THCOT-GLUC
Sample type	URINE
Result	5940
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	1
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Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112490001599
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-07
-----------------------	------------

Date of Collection	2014-MAR-29
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001621
Analyte	1-NA
Sample type	URINE
Result	129
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001621
Analyte	2-NA
Sample type	URINE
Result	43.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001621
Analyte	4-ABP
Sample type	URINE
Result	27.1
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001621
Analyte	O-TOL
Sample type	URINE
Result	207
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-29
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115190003623
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	1
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-MAR-29
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003614
----------------	----------------

Analyte	SBMA
---------	------

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

Result	.
--------	---

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

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-MAR-29
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003614
----------------	----------------

Analyte	SPMA
---------	------

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

Result	.
--------	---

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

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-MAR-29
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115180003623
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	.
--------	---

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

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-MAR-29
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115160001599
----------------	----------------

Analyte	CREATININE
---------	------------

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

Result	.
--------	---

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

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

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

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

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-MAR-29
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001959
Analyte	COT
Sample type	PLASMA
Result	442
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
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, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001959
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	22.3
--------	------

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

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

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

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, Daytona Beach,
Florida: 1235**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:14

Generated On: 20 Jul 2016 21:53:10

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Date of Visit

30 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

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

Pulse rate 68
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 115
mmHg

Blood Pressure (diastolic) 69
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	30 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	30 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: CoHb Blood Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	30 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: CO Breath Test (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	09:03
---	-------

Result(ppm)	14
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: CO Breath Test (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

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	12:00
---	-------

Result(ppm)	20
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: CO Breath Test (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

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	16:02
---	-------

Result(ppm)	28
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: CO Breath Test (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

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	20:01
---	-------

Result(ppm)	34
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: 24 hour urine collections

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Start Time	06:17
	hour:min 24-hour clock

End Date	31 MAR 2014
	DD/MMM/YYYY

End Time	06:16
	hour:min 24-hour clock

Volume	1638
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Sample Urine Collection

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 30
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?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Severe ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 2

Form: Cough Assessment

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 30
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, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004053
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	8.60
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	2
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment

2014 MAR 30

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:14
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Extremely ☒

2. Did cigarettes taste good?

Extremely ☒

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

Extremely ☒

4. Did smoking calm you down?

Quite a lot ☒

5. Did smoking make you feel more awake?

Quite a lot ☒

6. Did smoking make you feel less irritable?

Extremely ☒

7. Did smoking help you concentrate?

Moderately ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

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? Quite a lot ☐

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Type	QSU
------	-----

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

Date of assessment	2014 MAR 30
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:11
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Strongly agree <input checked="" type="radio"/>
---	---

3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Do not agree or disagree <input checked="" type="radio"/>
---	---

5. All I want right now is a cigarette	Strongly agree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

7. A cigarette would taste good now Strongly agree ☐

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 Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002675
Analyte	HPMA
Sample type	URINE
Result	1390
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002675
Analyte	CEMA
Sample type	URINE
Result	155
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002675
Analyte	HBMA
Sample type	URINE
Result	499
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003206
----------------	----------------

Analyte	NNAL
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Sample type	URINE
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Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-04
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Date of Collection	2014-MAR-30
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003206
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Analyte	NNN
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-04
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Date of Collection	2014-MAR-30
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:15

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112470001600
Analyte	HEMA
Sample type	URINE
Result	4.55
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001138
Analyte	COT
Sample type	URINE
Result	1990
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-31
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001138
Analyte	COT-GLUC
Sample type	URINE
Result	8260
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-31
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001138
Analyte	NIC
Sample type	URINE
Result	498
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-31
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001138
Analyte	NIC-GLUC
Sample type	URINE
Result	1270
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-31
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001138
Analyte	THCOT
Sample type	URINE
Result	6660
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-31
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001138
Analyte	THCOT-GLUC
Sample type	URINE
Result	5430
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-MAR-31
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112490001600
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-07
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Date of Collection	2014-MAR-30
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001622
Analyte	1-NA
Sample type	URINE
Result	102
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001622
Analyte	2-NA
Sample type	URINE
Result	31.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001622
Analyte	4-ABP
Sample type	URINE
Result	18.4
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001622
Analyte	O-TOL
Sample type	URINE
Result	188
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115190003624
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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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	AA99598-03
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Date of Collection	2014-MAR-30
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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, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003615
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003615
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115180003624
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Analyte	MHBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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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	AA99598-02
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Date of Collection	2014-MAR-30
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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, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115160001600
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Analyte	CREATININE
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Sample type	URINE
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Result	.
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Result Unit	MG/DL
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-14
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Date of Collection	2014-MAR-30
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001960
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Analyte	COT
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Sample type	PLASMA
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Result	366
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-01
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Date of Collection	2014-MAR-30
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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, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001960
Analyte	NIC
Sample type	PLASMA
Result	27.0
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-30
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Date of Visit

31 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

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

10:05
hour:min 24-hour clock

Pulse rate

61
beats per minute

Respiratory rate

20
breaths per minute

Blood Pressure (systolic)

107
mmHg

Blood Pressure (diastolic)

52
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	31 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	31 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: CoHb Blood Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:16

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	31 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: CO Breath Test (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

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	06:28
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: CO Breath Test (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

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	12:02
---	-------

Result(ppm)	12
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: CO Breath Test (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

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	16:03
---	-------

Result(ppm)	34
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: CO Breath Test (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

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)	33
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: 24 hour urine collections

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Start Time	06:16
	hour:min 24-hour clock

End Date	01 APR 2014
	DD/MMM/YYYY

End Time	06:01
	hour:min 24-hour clock

Volume	2257
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Sample Urine Collection

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 31
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?

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?

None ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 3

Form: Cough Assessment

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 31
DD/MMM/YYYY

Time of assessment

06:03
hour:min 24-hour clock

Assessment Status

Completed ☒

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

No ☒

If YES, please answer the following questions:

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

-9

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

Not Applicable ☒

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

Not Applicable ☒

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

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004054
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	8.40
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-31
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment

2014 MAR 31

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:02

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Extremely ☒

2. Did cigarettes taste good?

Extremely ☒

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

Extremely ☒

4. Did smoking calm you down?

Extremely ☒

5. Did smoking make you feel more awake?

Moderately ☒

6. Did smoking make you feel less irritable?

Little ☒

7. Did smoking help you concentrate?

A lot ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

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? Quite a lot ☐

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Type	QSU
------	-----

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

Date of assessment	2014 MAR 31
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:01
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Strongly agree <input checked="" type="radio"/>
--	---

3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Do not agree or disagree <input checked="" type="radio"/>
---	---

5. All I want right now is a cigarette	Strongly agree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

7. A cigarette would taste good now Strongly agree ☒

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 Strongly agree ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002676
Analyte	HPMA
Sample type	URINE
Result	891
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-31
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002676
Analyte	CEMA
Sample type	URINE
Result	116
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-31
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002676
Analyte	HBMA
Sample type	URINE
Result	411
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-31
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003207
----------------	----------------

Analyte	NNAL
---------	------

Sample type	URINE
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Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-MAR-31
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003207
----------------	----------------

Analyte	NNN
---------	-----

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

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-MAR-31
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112470001601
Analyte	HEMA
Sample type	URINE
Result	3.71
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-31
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001139
Analyte	COT
Sample type	URINE
Result	1760
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001139
Analyte	COT-GLUC
Sample type	URINE
Result	5860
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001139
Analyte	NIC
Sample type	URINE
Result	403
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001139
Analyte	NIC-GLUC
Sample type	URINE
Result	934
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001139
Analyte	THCOT
Sample type	URINE
Result	3950
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001139
Analyte	THCOT-GLUC
Sample type	URINE
Result	3620
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	3
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Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112490001601
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Analyte	3-OH BAP
---------	----------

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

Result	.
--------	---

Result Unit	FG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-MAR-31
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001623
Analyte	1-NA
Sample type	URINE
Result	79.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-31
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001623
Analyte	2-NA
Sample type	URINE
Result	23.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-31
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001623
Analyte	4-ABP
Sample type	URINE
Result	17.6
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-31
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001623
Analyte	O-TOL
Sample type	URINE
Result	140
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-31
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115190003625
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-MAR-31
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003616
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-31
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003616
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-31
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115180003625
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Analyte	MHBMA
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Sample type	URINE
-------------	-------

Result	.
--------	---

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

Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-MAR-31
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115160001601
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Analyte	CREATININE
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Sample type	URINE
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Result	.
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Result Unit	MG/DL
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-MAR-31
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001961
Analyte	COT
Sample type	PLASMA
Result	404
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-31
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001961
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	25.3
--------	------

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

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-MAR-31
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:17

Generated On: 20 Jul 2016 21:53:10

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Date of Visit

01 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

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

10:08
hour:min 24-hour clock

Pulse rate

68
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

115
mmHg

Blood Pressure (diastolic)

64
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date 01 APR 2014
DD/MMM/YYYY

Time 06:10
hour:min 24-hour clock

Q1. What is the highest level of education you have completed? High School Graduate ☒

Q2. What is your current occupational status? Looking for work, unemployed ☒

SPECIFY _____

Q3. How many people are currently living in your household, including yourself? 01

Q4. Of these people, how many are children? 00

Q5. Of these people, how many are adults? 01

Q6. Of the adults, how many bring income into the household? 01

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

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.

Less than \$10,000 ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: CoHb Blood Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 APR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: CO Breath Test (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

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)	12
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: CO Breath Test (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

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	12:00
---	-------

Result(ppm)	21
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: CO Breath Test (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

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)	41
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: CO Breath Test (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

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	20:00
---	-------

Result(ppm)	37
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: 24 hour urine collections

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Start Time	06:01
	hour:min 24-hour clock

End Date	02 APR 2014
	DD/MMM/YYYY

End Time	06:04
	hour:min 24-hour clock

Volume	1696
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Sample Urine Collection

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 01
DD/MMM/YYYY

Time of assessment

06:07
hour:min 24-hour clock

Assessment Status

Completed ☒

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

How have you been feeling over the past 24 hours?

Mild ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Severe ☒

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 4

Form: Cough Assessment

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 01
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, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004055
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	8.60
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	4
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment

2014 APR 01
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Extremely ☒

2. Did cigarettes taste good?

Extremely ☒

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

A lot ☒

4. Did smoking calm you down?

Quite a lot ☒

5. Did smoking make you feel more awake?

Little ☒

6. Did smoking make you feel less irritable?

Not at all ☒

7. Did smoking help you concentrate?

Not at all ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

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? Extremely ☐

12. Did you enjoy smoking? Extremely ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	01 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:14 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.	Agree <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.	Strongly agree <input type="radio"/>
--	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:05:18

Generated On: 20 Jul 2016 21:53:10

If you agree or strongly agree, please describe :

PRODUCT MENTHOL IS VERY
STRONG

4. The device is easy to use.

Strongly agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Agree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Type	QSU
------	-----

Date of Birth	(b) (6)
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Date of assessment	2014 APR 01
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:02
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

2. Nothing would be better than smoking a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

3. If it were possible I would probably smoke now	Strongly agree <input type="radio"/>
---	--------------------------------------

4. I could control things better right now if I could smoke	Strongly agree <input type="radio"/>
---	--------------------------------------

5. All I want right now is a cigarette	Strongly agree <input type="radio"/>
--	--------------------------------------

6. I have an urge for a cigarette	Strongly agree <input type="radio"/>
-----------------------------------	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

9. Smoking would make me less depressed Strongly agree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002677
Analyte	HPMA
Sample type	URINE
Result	1130
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-01
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002677
Analyte	CEMA
Sample type	URINE
Result	160
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-01
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002677
Analyte	HBMA
Sample type	URINE
Result	501
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-01
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003208
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-04
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Date of Collection	2014-APR-01
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	4
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Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003208
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Analyte	NNN
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-01
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	4
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Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112470001602
Analyte	HEMA
Sample type	URINE
Result	3.76
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-05
Date of Collection	2014-APR-01
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001140
Analyte	COT
Sample type	URINE
Result	1620
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	4
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Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001140
Analyte	COT-GLUC
Sample type	URINE
Result	6980
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	4
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Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001140
Analyte	NIC
Sample type	URINE
Result	305
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	4
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Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001140
Analyte	NIC-GLUC
Sample type	URINE
Result	1090
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	4
-----------------	---

Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001140
Analyte	THCOT
Sample type	URINE
Result	4470
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001140
Analyte	THCOT-GLUC
Sample type	URINE
Result	4080
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	4
-----------------	---

Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112490001602
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-07
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Date of Collection	2014-APR-01
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	4
-----------------	---

Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001624
Analyte	1-NA
Sample type	URINE
Result	100
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-01
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001624
Analyte	2-NA
Sample type	URINE
Result	31.8
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-01
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001624
Analyte	4-ABP
Sample type	URINE
Result	17.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-01
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001624
Analyte	O-TOL
Sample type	URINE
Result	174
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-01
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115190003626
----------------	----------------

Analyte	1-OHP
---------	-------

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

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	4
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-APR-01
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003617
----------------	----------------

Analyte	SBMA
---------	------

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

Result	.
--------	---

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

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	4
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-01
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003617
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-01
Date of Collection	2014-APR-01
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115180003626
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	.
--------	---

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

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	4
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-01
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115160001602
----------------	----------------

Analyte	CREATININE
---------	------------

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

Result	.
--------	---

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

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

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

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-01
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001962
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	400
--------	-----

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

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-01
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001962
Analyte	NIC
Sample type	PLASMA
Result	33.6
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-01
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:19

Generated On: 20 Jul 2016 21:53:10

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

Date of Visit

02 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

08:39
hour:min 24-hour clock

Pulse rate

68
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

109
mmHg

Blood Pressure (diastolic)

60
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:31
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:26
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	20:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:31
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:26
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	20:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:31
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	16:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 APR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: CO Breath Test (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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	06:22
---	-------

Result(ppm)	12
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: CO Breath Test (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	12:05
---	-------

Result(ppm)	23
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: CO Breath Test (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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	17:14
---	-------

Result(ppm)	36
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: CO Breath Test (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

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	20:05
---	-------

Result(ppm)	29
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Time of caffeine tablet intake	10:00
	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
02 APR 2014	16:00	Caffeine
02 APR 2014	16:00	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: 24 hour urine collections

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

Start Time	06:04
	hour:min 24-hour clock

End Date	03 APR 2014
	DD/MMM/YYYY

End Time	06:01
	hour:min 24-hour clock

Volume	1794
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Sample Urine Collection

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

Were samples for 24h collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

14

How many back up tubes were collected?

13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 02
DD/MMM/YYYY

Time of assessment

06:02
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?

Moderate ☐

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Cough Assessment

Data signed: (hfarmer1) 29 Mar 2015 19:05:22

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 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, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004056
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	4.90
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004057
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	7.80
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-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004058
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	8.40
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-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004059
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	7.70
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment

2014 APR 02

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Extremely ☒

2. Did cigarettes taste good?

Extremely ☒

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

Extremely ☒

4. Did smoking calm you down?

Extremely ☒

5. Did smoking make you feel more awake?

Little ☒

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?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

9. Did smoking make you dizzy? Very little ☐

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

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

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:43 hour:min 24-hour clock
--------------------	---------------------------------

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

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

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?	No <input type="radio"/>
--	--------------------------

How long has it been since you last smoked a cigarette, even one or two puffs?	Within the past month (less than 1 month ago) <input type="radio"/>
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

Not at all ☐

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:47 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? NEWPORT 100'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:47 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

Currently (last 3 months) ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:47 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

1 year ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:47 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

5 years ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:47 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

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, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:47 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?	18 Years
---	----------

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

Years	<hr/>
-------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

15 years ago ☒

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

None ☒

Manufactured Cigarettes
per day

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:47 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?	18 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, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

20 years ago ☒

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

None ☒

Manufactured Cigarettes
per day

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

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

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

Date of assessment	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:47 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?	18 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, Daytona Beach, Florida: 1235

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years 00 Years

Months 00 Months

Days 00 Days

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

Time More than 20 years ago ☒

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

Manufactured Cigarettes
per day

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

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:20

Generated On: 20 Jul 2016 21:53:10

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Supplemental Questions

Data signed: (hfarmer1) 29 Mar 2015 19:05:21

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

02 APR 2014
DD/MMM/YYYY

Time of assessment

20:49

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

03 minutes

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:21

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 02 APR 2014
DD/MMM/YYYY

Time of assessment 20:49

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:21

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 02 APR 2014
DD/MMM/YYYY

Time of assessment 20:49

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:21

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 02 APR 2014
DD/MMM/YYYY

Time of assessment 20:49

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:21

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 02 APR 2014
DD/MMM/YYYY

Time of assessment 20:49

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:21

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 02 APR 2014
DD/MMM/YYYY

Time of assessment 20:49

1. How long it takes for the subject to complete the SQ 03 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:21

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 02 APR 2014
DD/MMM/YYYY

Time of assessment 20:49

1. How long it takes for the subject to complete the SQ 03 minutes

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 APR 02
Time of assessment hour:min 24-hour clock	20:02
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Strongly agree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Strongly agree <input type="radio"/>
3. If it were possible I would probably smoke now	Strongly agree <input type="radio"/>
4. I could control things better right now if I could smoke	Strongly agree <input type="radio"/>
5. All I want right now is a cigarette	Strongly agree <input type="radio"/>
6. I have an urge for a cigarette	Strongly agree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

7. A cigarette would taste good now Strongly agree ☐

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

9. Smoking would make me less depressed Strongly agree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002678
Analyte	HPMA
Sample type	URINE
Result	1160
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002678
Analyte	CEMA
Sample type	URINE
Result	139
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002678
Analyte	HBMA
Sample type	URINE
Result	653
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003209
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-04
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Date of Collection	2014-APR-02
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003209
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Analyte	NNN
---------	-----

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

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-02
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112470001603
Analyte	HEMA
Sample type	URINE
Result	3.26
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-05
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001141
Analyte	COT
Sample type	URINE
Result	2010
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001141
Analyte	COT-GLUC
Sample type	URINE
Result	8240
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001141
Analyte	NIC
Sample type	URINE
Result	845
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
-----------------	---

Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001141
Analyte	NIC-GLUC
Sample type	URINE
Result	1220
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
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Urine End Day	6
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001141
Analyte	THCOT
Sample type	URINE
Result	4840
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
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Urine End Day	6
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001141
Analyte	THCOT-GLUC
Sample type	URINE
Result	4500
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112490001603
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-APR-02
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
<hr/>	
Urine End Day	6
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112500000437
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	1080
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-APR-02
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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, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112500000437
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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Result	1510
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-APR-02
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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, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001625
Analyte	1-NA
Sample type	URINE
Result	89.1
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001625
Analyte	2-NA
Sample type	URINE
Result	28.1
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001625
Analyte	4-ABP
Sample type	URINE
Result	15.4
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001625
Analyte	O-TOL
Sample type	URINE
Result	162
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112530000508
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Analyte	11-DTXB2
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-11
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Date of Collection	2014-APR-02
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:23

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112540000501
Analyte	IPF2A-III
Sample type	URINE
Result	316
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-12
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05113320000218
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Analyte	AMES
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Sample type	URINE
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Result	.
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Result Unit	REV/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	COUNT
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-15
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Date of Collection	2014-APR-02
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115190003627
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-03
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003618
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-01
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

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

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003618
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-01
Date of Collection	2014-APR-02
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115180003627
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Analyte	MHBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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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	AA99598-02
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Date of Collection	2014-APR-02
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Timepoint-minutes	
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Urine Start Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115160001603
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Analyte	CREATININE
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Sample type	URINE
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Result	.
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Result Unit	MG/DL
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-14
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Date of Collection	2014-APR-02
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001963
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Analyte	COT
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Sample type	PLASMA
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Result	389
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
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Date of Collection	2014-APR-02
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Timepoint-minutes	-15
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001963
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Analyte	NIC
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Sample type	PLASMA
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Result	3.75
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-01
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Date of Collection	2014-APR-02
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Timepoint-minutes	-15
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001964
Analyte	COT
Sample type	PLASMA
Result	392
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	2
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001964
Analyte	NIC
Sample type	PLASMA
Result	28.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	2
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001965
Analyte	COT
Sample type	PLASMA
Result	382
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	4
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001965
Analyte	NIC
Sample type	PLASMA
Result	25.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	4
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001966
Analyte	COT
Sample type	PLASMA
Result	404
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001966
Analyte	NIC
Sample type	PLASMA
Result	24.7
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001967
Analyte	COT
Sample type	PLASMA
Result	378
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	8
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001967
Analyte	NIC
Sample type	PLASMA
Result	17.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	8
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001968
Analyte	COT
Sample type	PLASMA
Result	373
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	10
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001968
Analyte	NIC
Sample type	PLASMA
Result	21.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	10
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001969
Analyte	COT
Sample type	PLASMA
Result	394
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	12
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001969
Analyte	NIC
Sample type	PLASMA
Result	26.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	12
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001970
Analyte	COT
Sample type	PLASMA
Result	372
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	14
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001970
Analyte	NIC
Sample type	PLASMA
Result	20.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	14
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001971
Analyte	COT
Sample type	PLASMA
Result	375
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001971
Analyte	NIC
Sample type	PLASMA
Result	38.6
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 29 Mar 2015 19:05:24

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Date of Visit

03 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 APR 2014
---------------------	-------------

Scheduled Time	T0 + 20H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	02:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 APR 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 APR 2014
---------------------	-------------

Scheduled Time	T0 + 20H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	02:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 APR 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: CoHb Blood Sample <prior to gas transfer and product>

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 APR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterols

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?	Yes <input checked="" type="radio"/>
--	--------------------------------------

Date DD/MMM/YYYY	03 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:30
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 6

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

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

03 APR 2014

06:30

trans-3'-hydroxyc
otinine

03 APR 2014

06:30

cotinine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Risk Marker: sICAM-1

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 03
DD/MMM/YYYY

Time of assessment

06:08
hour:min 24-hour clock

Assessment Status

Completed ☒

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

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Severe ☐

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? 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, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 6

Form: Cough Assessment

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 03
DD/MMM/YYYY

Time of assessment

06:07
hour:min 24-hour clock

Assessment Status

Completed ☒

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

No ☒

If YES, please answer the following questions:

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

-9

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

Not Applicable ☒

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

Not Applicable ☒

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

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:30
hour:min 24-hour clock

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

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

Yes ☒

Time of Sample Collection

06:30
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 29 Mar 2015 19:05:25

Generated On: 20 Jul 2016 21:53:10

Was a Bio-banking sample for nasal epithelial collection/buccal collection taken?	Yes <input type="radio"/>
---	---------------------------

Time of Buccal Collection	10:25
	hour:min 24-hour clock

Time of Nasal Epithelial Collection	10:22
	hour:min 24-hour clock

Was the subject fasting for at least 30 minutes at time of sample collection?	Yes <input type="radio"/>
---	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
-------------------------	------------

Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCRL
--------------	---------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	9.46
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
-------------------------	------------

Analyte	24(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	24RHCRL
--------------	---------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	6.56
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
-------------------------	------------

Analyte	25-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	25HCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	4.70
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
-------------------------	------------

Analyte	27-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	27HCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	11.60
-------------------------------	-------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
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Analyte	4B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	4BHCRL
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Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	10.66
-------------------------------	-------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
-------------------------	------------

Analyte	5A,6A-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5A6AECNL
--------------	----------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.46
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
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Analyte	5B,6B-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5B6BECNL
--------------	----------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	26.83
-------------------------------	-------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
-------------------------	------------

Analyte	6A-HYDROXY-5A-CHOLESTAN OL
---------	-------------------------------

Analyte code	6AH5ACNL
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Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	13.70
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
-------------------------	------------

Analyte	7-KETOCHOLESTEROL
---------	-------------------

Analyte code	7KCRL
--------------	-------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	15.43
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
-------------------------	------------

Analyte	7A-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7AHCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	13.46
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
-------------------------	------------

Analyte	7B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7BHCRL
--------------	--------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.86
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 21:53:10

Sample Accession number	3281675115
-------------------------	------------

Analyte	CHOLESTEROL
---------	-------------

Analyte code	CHOL
--------------	------

Result	
--------	--

Result Unit	MG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	0.50
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004060
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	6.90
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	6
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

Date of Birth

(b) (6)

Date of assessment

2014 APR 03
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

06:09
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Extremely ☒

2. Did cigarettes taste good?

Extremely ☒

3. Did you enjoy the sensation in your throat and chest?

Extremely ☒

4. Did smoking calm you down?

Not at all ☒

5. Did smoking make you feel more awake?

Extremely ☒

6. Did smoking make you feel less irritable?

Extremely ☒

7. Did smoking help you concentrate?

Not at all ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

9. Did smoking make you dizzy? Very little ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a cigarette? Quite a lot ☐

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

Type	QSU
------	-----

Date of Birth	(b) (6)
---------------	---------

Date of assessment	2014 APR 03
--------------------	-------------

DD/MMM/YYYY

Time of assessment	06:11
--------------------	-------

hour:min 24-hour clock

Assessment Status	Completed <input type="radio"/>
-------------------	---------------------------------

1. I have a desire for a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

2. Nothing would be better than smoking a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

3. If it were possible I would probably smoke now	Strongly agree <input type="radio"/>
---	--------------------------------------

4. I could control things better right now if I could smoke	Strongly agree <input type="radio"/>
---	--------------------------------------

5. All I want right now is a cigarette	Strongly agree <input type="radio"/>
--	--------------------------------------

6. I have an urge for a cigarette	Strongly agree <input type="radio"/>
-----------------------------------	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Strongly agree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY6
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	274.6
Reported Numeric Result	274.6
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:26

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001972
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	384
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	20
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-03
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001972
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	7.87
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	20
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-03
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001973
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	372
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	24
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-03
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 21:53:10

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001973
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	3.30
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	24
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-03
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 21:53:10

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112520000437
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	360
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-APR-03
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112520000437
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	142
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-APR-03
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Generated On: 20 Jul 2016 21:53:10

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Date of Visit

03 APR 2014
DD/MMM/YYYY

Discharge Time

11:13
hour:min 24-hour clock

Is the subject continuing in the ambulatory period?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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 07:57
hour:min 24-hour clock

Pulse rate 61
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 116
mmHg

Blood Pressure (diastolic) 70
mmHg

Vital Signs Position of Subject Supine ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Back ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Weight

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

03 APR 2014
DD/MMM/YYYY

Time of assessment

10:39
hour:min 24-hour clock

Weight

64.0
kg

BMI

20.2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 62
beats per minute

QRS Interval 109
msec

QT Interval 424
msec

QTcB Interval 434
msec

PR Interval 175
msec

QTcF Interval 430
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

If Not Clinically significant or clinically Significant, Please
specify the finding(s) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Gas Transfer

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Was the Gas Transfer performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Date of assessment 03 APR 2014
DD/MMM/YYYY

Time of assessment 05:29

DLCO value 17.33
ml/min/mmHg

KCO value 0.72
mmol/min/kPa/L

DLCO/VA value 2.09
mL/min/mmHg/L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Clinically significant ☒

If Not Clinically Significant or Clinically Significant, Please specify the finding(s) MODERATELY SEVERE
DECREASE DLCO

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

Were the Lung Volume Measurements performed?

Yes ☒

If No, please specify the reason: _____

Category _____

Position

SITTING

Date of assessment
DD/MMM/YYYY

03 APR 2014

Time of assessment

05:44

VC value

6.00
L

TLC value

10.49
L

IC value

3.21
L

FRC value

7.28
L

Interpretation _____

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

If Not Clinically Significant or Clinically Significant, Please CANNOT INTERPERT RESULTS
specify the finding(s) NOT PHYSIOLOGIC

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

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

03 APR 2014

Time of assessment

06:13

Name of bronchodilator

ALBUTEROL SULFATE

Dose

180 MCG

Predicted FVC value

5.56
L

Best measured FVC value

6.00
L

Percent of predicted FVC value

107
%

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

Best measured FEV1 value	4.61 L
--------------------------	-----------

Predicted FEV1 value	4.59 L
----------------------	-----------

Percent of predicted FEV1 value	100 %
---------------------------------	----------

Calculated ratio between FEV1/FVC	_____
-----------------------------------	-------

MEF 25/75 value	4.02 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, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (hfarmer1) 29 Mar 2015 19:05:27

Generated On: 20 Jul 2016 21:53:10

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	07:59
	hour:min 24-hour clock

Result	27
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	76
Reported Numeric Result	76
Reference Range low	44
Reference Range high	249
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
--------------	-----------------

Lab Test ID	RCT142
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	84
Reported Numeric Result	84
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	136
Reported Numeric Result	136
Reference Range low	128
Reference Range high	236
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT12
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	6.9
Reported Numeric Result	6.9
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT13
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1407
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	58
Reported Numeric Result	58
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1408
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	147
Reported Numeric Result	147
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT15
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	141
Reported Numeric Result	141
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT16
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.0
Reported Numeric Result	4.0
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
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Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" 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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	GGT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
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Actual Collection Date	2014 04 03
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Actual Collection Time	06:30
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
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Reported Text Result	1.0
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Reported Numeric Result	1.0
-------------------------	-----

Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
-------------	-------

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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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
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Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	10
Reported Numeric Result	10
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	W816751
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Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816751

Actual Collection Date 2014 04 03

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	20
Reported Numeric Result	20
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
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Actual Collection Date	2014 04 03
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Actual Collection Time	06:30
------------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.52
Reported Numeric Result	0.52
Reference Range low	0.12
Reference Range high	0.92
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT102
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT11
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.03
Reported Numeric Result	1.03
Reference Range low	0.00
Reference Range high	0.57
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.09
Reported Numeric Result	0.09
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT13
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	203
Reported Numeric Result	203
Reference Range low	140
Reference Range high	400
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT15
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	51.3
Reported Numeric Result	51.3
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	34.2
Reported Numeric Result	34.2
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
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, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	9.1
Reported Numeric Result	9.1
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT19
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.8
Reported Numeric Result	0.8
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	40
Reported Numeric Result	40
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MCV
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	88
Reported Numeric Result	88
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

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, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13.5
Reported Numeric Result	13.5
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT7
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	11.26
Reported Numeric Result	11.26
Reference Range low	3.80
Reference Range high	10.70
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT71
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

RBC MORPHOLOGY 1

Test ID

Test Status

Done 

Reported Text Result

NORMOCYTIC

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT8
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	5.78
Reported Numeric Result	5.78
Reference Range low	1.96
Reference Range high	7.23
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT9
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	3.85
Reported Numeric Result	3.85
Reference Range low	0.91
Reference Range high	4.28
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR NITRITE

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT2
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.027
Reported Numeric Result	1.027
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT3
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT5
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR GLUCOSE

Test ID

Test Status

Done 

Reported Text Result

NORMAL

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

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	W816751
--------------	---------

Actual Collection Date	2014 04 03
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR BILIRUBIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:05:28

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

Visit Not Done	False
----------------	-------

If Not Done, Specify Reason	<hr/>
-----------------------------	-------

Date of Visit	27 APR 2014 DD/MMM/YYYY
---------------	----------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

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

27 APR 2014
DD/MMM/YYYY

Time of assessment

14:38
hour:min 24-hour clock

Pulse rate

67
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

112
mmHg

Blood Pressure (diastolic)

64
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

Date	28 APR 2014 DD/MMM/YYYY
------	----------------------------

Has the subject received advices on the risks of smoking?	Yes <input type="radio"/>
---	---------------------------

Has a debriefing been performed about THS 2.2?	Yes <input type="radio"/>
--	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 APR 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 APR 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 APR 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 APR 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 APR 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Skin ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of Assessment 27 APR 2014
DD/MMM/YYYY

System Back ☐

Outcome Normal ☐

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (13)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (14)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (15)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (16)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (17)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (18)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Physical Examination (19)

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Weight

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

Time of assessment

14:40
hour:min 24-hour clock

Weight

65.7
kg

BMI

20.8

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 19:05:38

Generated On: 20 Jul 2016 21:53:10

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 APR 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

75
beats per minute

QRS Interval

104
msec

QT Interval

397
msec

QTcB Interval

445
msec

PR Interval

176
msec

QTcF Interval

428
msec

Interpretation

Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 19:05:38

Generated On: 20 Jul 2016 21:53:10

If Abnormal, Clinical Significance _____

If Not Clinically significant or clinically Significant, Please
specify the finding(s) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Haematology

Data signed: (hfarmer1) 29 Mar 2015 19:05:38

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Clinical Chemistry

Data signed: (hfarmer1) 29 Mar 2015 19:05:38

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Urine analysis

Data signed: (hfarmer1) 29 Mar 2015 19:05:38

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	10:00
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	10:00
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: CoHb Blood Sample <D30_D60>

Data signed: (hfarmer1) 29 Mar 2015 19:05:38

Generated On: 20 Jul 2016 21:53:10

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 APR 2014
---------------------	-------------

Timepoint	10:00 - 11:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	10:00
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: CO Breath Test

Data signed: (hfarmer1) 29 Mar 2015 19:05:38

Generated On: 20 Jul 2016 21:53:10

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Date of Assessment	27 APR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Actual Time of Assessment	10:05 hour:min 24-hour clock
---------------------------	---------------------------------

Result	26 ppm
--------	-----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1

Data signed: (hfarmer1) 29 Mar 2015 19:05:39

Generated On: 20 Jul 2016 21:53:10

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: 24 hour urine collections

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

Start Date	27 APR 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	09:08 hour:min 24-hour clock
------------	---------------------------------

End Date	28 APR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	09:00 hour:min 24-hour clock
----------	---------------------------------

Volume	2127 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Sample Urine Collection

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	50
Reported Numeric Result	50
Reference Range low	44
Reference Range high	249
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
--------------	-----------------

Lab Test ID	RCT142
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	87
Reported Numeric Result	87
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	126
Reported Numeric Result	126
Reference Range low	128
Reference Range high	236
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Low ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input type="checkbox"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT12
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT13
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.1
Reported Numeric Result	4.1
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1407
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	54
Reported Numeric Result	54
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1408
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	150
Reported Numeric Result	150
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT15
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	142
Reported Numeric Result	142
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT29
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name

DIRECT BILIRUBIN

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
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Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	11
Reported Numeric Result	11
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT392
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
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Reported Text Result	1.0
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Reported Numeric Result	1.0
-------------------------	-----

Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
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Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	12
Reported Numeric Result	12
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	17
Reported Numeric Result	17
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	16
Reported Numeric Result	16
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	X312825
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Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.62
Reported Numeric Result	0.62
Reference Range low	0.12
Reference Range high	0.92
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT102
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	32
Reported Numeric Result	32
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
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Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT11
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.64
Reported Numeric Result	0.64
Reference Range low	0.00
Reference Range high	0.57
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.09
Reported Numeric Result	0.09
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT13
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	184
Reported Numeric Result	184
Reference Range low	140
Reference Range high	400
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	42.1
Reported Numeric Result	42.1
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	43.0
Reported Numeric Result	43.0
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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
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Actual Collection Date	2014 04 28
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Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.9
Reported Numeric Result	6.9
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.1
Reported Numeric Result	7.1
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.0
Reported Numeric Result	1.0
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	43
Reported Numeric Result	43
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.7
Reported Numeric Result	4.7
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

MCV

Test ID

Test Status

Done 

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13.9
Reported Numeric Result	13.9
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	9.00
Reported Numeric Result	9.00
Reference Range low	3.80
Reference Range high	10.70
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

RBC MORPHOLOGY 1

Test ID

Test Status

Done 

Reported Text Result

NORMOCYTIC

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT8
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.79
Reported Numeric Result	3.79
Reference Range low	1.96
Reference Range high	7.23
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT9
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.86
Reported Numeric Result	3.86
Reference Range low	0.91
Reference Range high	4.28
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT10
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR NITRITE

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.012
Reported Numeric Result	1.012
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT5
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR GLUCOSE

Test ID

Test Status

Done 

Reported Text Result

NORMAL

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

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	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR BILIRUBIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:05:46

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004061
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	6.90
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-APR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 28 APR 2014
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment 06:22
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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment
DD/MMM/YYYY

28 APR 2014
DD/MMM/YYYY

Time of assessment

06:23
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, Daytona Beach, Florida: 1235

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

	Result
3. Depressed Mood, sad	None
4. Desire or craving to smoke	Severe
5. Difficulty concentrating	None
6. Increased appetite, hungry, weight gain	None
7. Insomnia, sleep problems, awakening at night	None
8. Restless	None
9. Impatient	None

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

	Result
10. Constipation	None
11. Dizziness	None
12. Coughing	None
13. Dreaming or nightmares	None
14. Nausea	None
15. Sore throat	None

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:17
hour:min 24-hour clock

1. Are you currently a smoker? Yes, I currently smoke ☒

2. In the last year, how many times have you quit
smoking for at least 24 hours? 0

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 30

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Type

HUMAN SMOKING
TOPOGRAPHY
QUESTIONNAIRE

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT IN MCC ARM

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 APR 2014
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:16
--------------------	-------

hour:min 24-hour clock

1. I have a desire for a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

2. Nothing would be better than smoking a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

3. If it were possible I would probably smoke now	Strongly agree <input type="radio"/>
---	--------------------------------------

4. I could control things better right now if I could smoke	Strongly agree <input type="radio"/>
---	--------------------------------------

5. All I want right now is a cigarette	Strongly agree <input type="radio"/>
--	--------------------------------------

6. I have an urge for a cigarette	Strongly agree <input type="radio"/>
-----------------------------------	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:05:41

Generated On: 20 Jul 2016 21:53:10

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Strongly agree ☐

9. Smoking would make me less depressed Strongly agree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment

27 APR 2014
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:15
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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 Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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 Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 APR 2014
DD/MMM/YYYY

Time of assessment 20:15
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)

Data signed: (hfarmer1) 29 Mar 2015 19:05:40

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment

27 APR 2014
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:15
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

Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
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Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	270
Reported Numeric Result	270
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	12.74
Reported Numeric Result	12.74
Reference Range low	3.70
Reference Range high	13.90
Range Units	UMOL/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	246.3
Reported Numeric Result	246.3
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done ☒

Reported Text Result

49

Reported Numeric Result

49

Reference Range low

30

Reference Range high

63

Range Units

MG/DL

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

C-REACTIVE PROTEIN (N
HS)-QT

Test ID

Test Status

Done 

Reported Text Result

0.095

Reported Numeric Result

0.095

Reference Range low

Reference Range high

<=0.287

Range Units

MG/DL

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312825
--------------	---------

Actual Collection Date	2014 04 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	73
----------------------	----

Reported Numeric Result	73
-------------------------	----

Reference Range low	66
---------------------	----

Reference Range high	147
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:05:42

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002679
Analyte	HPMA
Sample type	URINE
Result	1040
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-27
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002679
Analyte	CEMA
Sample type	URINE
Result	142
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-27
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002679
Analyte	HBMA
Sample type	URINE
Result	516
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-27
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003210
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
-----------------	----

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003210
----------------	----------------

Analyte	NNN
---------	-----

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
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Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112470001604
Analyte	HEMA
Sample type	URINE
Result	5.67
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-05
Date of Collection	2014-APR-27
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 30

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001142
Analyte	COT
Sample type	URINE
Result	2400
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001142
Analyte	COT-GLUC
Sample type	URINE
Result	6090
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 30

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001142
Analyte	NIC
Sample type	URINE
Result	1290
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
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Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001142
Analyte	NIC-GLUC
Sample type	URINE
Result	1190
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001142
Analyte	THCOT
Sample type	URINE
Result	3640
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
-----------------	----

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001142
Analyte	THCOT-GLUC
Sample type	URINE
Result	2520
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112490001604
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Analyte	3-OH BAP
---------	----------

Sample type	URINE
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Result	.
--------	---

Result Unit	FG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-APR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
-----------------	----

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001626
Analyte	1-NA
Sample type	URINE
Result	55.8
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-27
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001626
Analyte	2-NA
Sample type	URINE
Result	18.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-27
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001626
Analyte	4-ABP
Sample type	URINE
Result	9.72
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-27
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001626
Analyte	O-TOL
Sample type	URINE
Result	96.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-27
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112530000509
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Analyte	11-DTXB2
---------	----------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-11
-----------------------	------------

Date of Collection	2014-APR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
-----------------	----

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112540000502
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Analyte	IPF2A-III
---------	-----------

Sample type	URINE
-------------	-------

Result	280
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-12
-----------------------	------------

Date of Collection	2014-APR-27
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	30
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115190003628
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Analyte	1-OHP
---------	-------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-APR-27
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	30
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003619
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99598-01
Date of Collection	2014-APR-27
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003619
----------------	----------------

Analyte	SPMA
---------	------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115180003628
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Analyte	MHBMA
---------	-------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-27
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	30
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115160001604
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Analyte	CREATININE
---------	------------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	MG/DL
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
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Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	30
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Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001974
Analyte	COT
Sample type	PLASMA
Result	384
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-27
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001974
Analyte	NIC
Sample type	PLASMA
Result	28.6
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-27
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:06

Generated On: 20 Jul 2016 21:53:10

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Date of Visit

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Visit Not Done	False
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If Not Done, Specify Reason	<hr/>
-----------------------------	-------

Date of Visit	27 MAY 2014 DD/MMM/YYYY
---------------	----------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Vital Signs

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

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

27 MAY 2014
DD/MMM/YYYY

Time of assessment

14:38
hour:min 24-hour clock

Pulse rate

65
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

108
mmHg

Blood Pressure (diastolic)

61
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 29 Mar 2015 19:06:12

Generated On: 20 Jul 2016 21:53:10

Date	28 MAY 2014 DD/MMM/YYYY
------	----------------------------

Has the subject received advices on the risks of smoking?	Yes <input type="radio"/>
---	---------------------------

Has a debriefing been performed about THS 2.2?	Yes <input type="radio"/>
--	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

System

HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (7)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (8)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (9)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 2014
DD/MMM/YYYY

System Skin ☒

Outcome Abnormal ☒

Abnormal, please specify ABRASION RIGHT PALM
MEASURING 15X15MM

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (11)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (12)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (13)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (14)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 27 MAY 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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (15)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (16)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (17)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (18)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Physical Examination (19)

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Weight

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

Time of assessment

15:16
hour:min 24-hour clock

Weight

65.8
kg

BMI

20.8

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

27 MAY 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

71
beats per minute

QRS Interval

110
msec

QT Interval

413
msec

QTcB Interval

451
msec

PR Interval

167
msec

QTcF Interval

438
msec

Interpretation

Abnormal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

If Abnormal, Clinical Significance

Not clinically significant ☒

If Not Clinically significant or clinically Significant, Please
specify the finding(s)

SINUS RHYTHM WITH
INTRAVENTRICULAR
CONDUCTION DELAY, NO
MYOCARDIAL INFARCTION

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Haematology

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Clinical Chemistry

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Urine analysis

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 MAY 2014
---------------------	-------------

Time hour:min 24-hour clock	10:08
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 MAY 2014
---------------------	-------------

Time hour:min 24-hour clock	10:08
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: CoHb Blood Sample <D30_D60>

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	27 MAY 2014
---------------------	-------------

Timepoint	10:00 - 11:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	10:08
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: CO Breath Test

Data signed: (hfarmer1) 29 Mar 2015 19:06:07

Generated On: 20 Jul 2016 21:53:10

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Date of Assessment	27 MAY 2014 DD/MMM/YYYY
---------------------------	----------------------------

Actual Time of Assessment	10:11 hour:min 24-hour clock
---------------------------	---------------------------------

Result	28 ppm
--------	-----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1

Data signed: (hfarmer1) 29 Mar 2015 19:06:08

Generated On: 20 Jul 2016 21:53:10

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 MAY 2014
---------------------	-------------

Time hour:min 24-hour clock	06:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: 24 hour urine collections

Data signed: (hfarmer1) 29 Mar 2015 19:06:12

Generated On: 20 Jul 2016 21:53:10

Start Date	27 MAY 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	09:10 hour:min 24-hour clock
------------	---------------------------------

End Date	28 MAY 2014 DD/MMM/YYYY
----------	----------------------------

End Time	08:57 hour:min 24-hour clock
----------	---------------------------------

Volume	1658 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Sample Urine Collection

Data signed: (hfarmer1) 29 Mar 2015 19:06:12

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
--------------	-----------------

Lab Test ID	RCT142
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	139
Reported Numeric Result	139
Reference Range low	128
Reference Range high	236
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input type="checkbox"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT12
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT13
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.8
Reported Numeric Result	3.8
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1407
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	63
Reported Numeric Result	63
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1408
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	179
Reported Numeric Result	179
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT15
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	141
Reported Numeric Result	141
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 60

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT29
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

DIRECT BILIRUBIN

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT3
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	12
Reported Numeric Result	12
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT392
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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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	<hr/>
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Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	11
Reported Numeric Result	11
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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"/>
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Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT6
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.46
Reported Numeric Result	0.46
Reference Range low	0.12
Reference Range high	0.92
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT100
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT102
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT11
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.60
Reported Numeric Result	0.60
Reference Range low	0.00
Reference Range high	0.57
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT12
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.10
Reported Numeric Result	0.10
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10 ³ /UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT13
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	243
Reported Numeric Result	243
Reference Range low	140
Reference Range high	400
Range Units	X10 ³ /UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
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Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
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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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	51.9
Reported Numeric Result	51.9
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
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Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	35.9
Reported Numeric Result	35.9
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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.9
Reported Numeric Result	4.9
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
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Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	6.3
Reported Numeric Result	6.3
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
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Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	1.0
Reported Numeric Result	1.0
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 60

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
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Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	43
Reported Numeric Result	43
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
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Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.7
Reported Numeric Result	4.7
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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) <div></div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input type="radio"/>
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Accession ID	X312832
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Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	90
Reported Numeric Result	90
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14.2
Reported Numeric Result	14.2
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	9.53
Reported Numeric Result	9.53
Reference Range low	3.80
Reference Range high	10.70
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (33)


Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

RBC MORPHOLOGY 1

Test ID

Test Status

Done 

Reported Text Result

NORMOCYTIC

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
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Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.95
Reported Numeric Result	4.95
Reference Range low	1.96
Reference Range high	7.23
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.42
Reported Numeric Result	3.42
Reference Range low	0.91
Reference Range high	4.28
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (36)

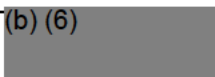
Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID X312832

Actual Collection Date 2014 05 28

Actual Collection Time 06:15

Specimen Condition

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT10

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR NITRITE

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (37)

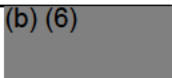
Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X312832

Actual Collection Date 2014 05 28

Actual Collection Time 06:15

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	1.011
Reported Numeric Result	1.011
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312832

Actual Collection Date 2014 05 28

Actual Collection Time 06:15

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (40)

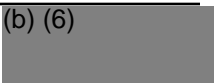
Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

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	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312832

Actual Collection Date 2014 05 28

Actual Collection Time 06:15

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR GLUCOSE

Test ID

Test Status

Done 

Reported Text Result

NORMAL

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X312832

Actual Collection Date 2014 05 28

Actual Collection Time 06:15

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT7

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

UR BILIRUBIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 29 Mar 2015 19:06:17

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:37

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115150004062
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)	10
Day of Visit	60
Celerion Study Number	AA99128-16
Date of Collection	2014-MAY-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:37

Generated On: 20 Jul 2016 21:53:10

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:06:09

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 28 MAY 2014
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment 06:51
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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:06:09

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Folder: Day 60

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment
DD/MMM/YYYY

28 MAY 2014
DD/MMM/YYYY

Time of assessment

06:51
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, Daytona Beach, Florida: 1235

Folder: Day 60

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

	Result
3. Depressed Mood, sad	None
4. Desire or craving to smoke	None
5. Difficulty concentrating	None
6. Increased appetite, hungry, weight gain	None
7. Insomnia, sleep problems, awakening at night	None
8. Restless	None
9. Impatient	None

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 60

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

	Result
10. Constipation	None
11. Dizziness	None
12. Coughing	None
13. Dreaming or nightmares	None
14. Nausea	None
15. Sore throat	None

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 29 Mar 2015 19:06:12

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:28
hour:min 24-hour clock

1. Are you currently a smoker? Yes, I currently smoke ☒

2. In the last year, how many times have you quit
smoking for at least 24 hours? 0

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 60

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	27 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:26 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"/>
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

If you agree or strongly agree, please describe : _____

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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:06:12

Generated On: 20 Jul 2016 21:53:10

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	
-----------------	--

Date of assessment	27 MAY 2014
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:27
--------------------	-------

hour:min 24-hour clock

1. I have a desire for a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

2. Nothing would be better than smoking a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

3. If it were possible I would probably smoke now	Strongly agree <input type="radio"/>
---	--------------------------------------

4. I could control things better right now if I could smoke	Strongly agree <input type="radio"/>
---	--------------------------------------

5. All I want right now is a cigarette	Strongly agree <input type="radio"/>
--	--------------------------------------

6. I have an urge for a cigarette	Strongly agree <input type="radio"/>
-----------------------------------	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:06:12

Generated On: 20 Jul 2016 21:53:10

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Strongly agree ☐

9. Smoking would make me less depressed Strongly agree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment

27 MAY 2014

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:23

hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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 Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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 Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)

Data signed: (hfarmer1) 29 Mar 2015 19:06:10

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 27 MAY 2014
DD/MMM/YYYY

Time of assessment 20:23
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 Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13


Generated On: 20 Jul 2016 21:53:10

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done 

Reported Text Result

41

Reported Numeric Result

41

Reference Range low

31

Reference Range high

63

Range Units

MG/DL

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	C-REACTIVE PROTEIN (N HS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.220
Reported Numeric Result	0.220
Reference Range low	
Reference Range high	<=0.287
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 60

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	269
Reported Numeric Result	269
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	8.82
Reported Numeric Result	8.82
Reference Range low	3.70
Reference Range high	13.90
Range Units	UMOL/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	248.0
Reported Numeric Result	248.0
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1235
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312832
--------------	---------

Actual Collection Date	2014 05 28
------------------------	------------

Actual Collection Time	06:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	81
----------------------	----

Reported Numeric Result	81
-------------------------	----

Reference Range low	70
---------------------	----

Reference Range high	165
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:13

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002680
Analyte	HPMA
Sample type	URINE
Result	792
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-03
Date of Collection	2014-MAY-27
Timepoint-minutes	
Urine Start Day	60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002680
Analyte	CEMA
Sample type	URINE
Result	117
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-03
Date of Collection	2014-MAY-27
Timepoint-minutes	
Urine Start Day	60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112450002680
Analyte	HBMA
Sample type	URINE
Result	491
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-03
Date of Collection	2014-MAY-27
Timepoint-minutes	
Urine Start Day	60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 29 Mar 2015 19:06:37

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:37

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003211
----------------	----------------

Analyte	NNAL
---------	------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-MAY-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:37

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:37

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112460003211
----------------	----------------

Analyte	NNN
---------	-----

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-MAY-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:37

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 29 Mar 2015 19:06:37

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:37

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112470001605
Analyte	HEMA
Sample type	URINE
Result	3.41
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-05
Date of Collection	2014-MAY-27
Timepoint-minutes	
Urine Start Day	60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:37

Generated On: 20 Jul 2016 21:53:10

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001143
Analyte	COT
Sample type	URINE
Result	1600
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001143
----------------	----------------

Analyte	COT-GLUC
---------	----------

Sample type	URINE
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Result	3500
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAY-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 60

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001143
Analyte	NIC
Sample type	URINE
Result	238
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 60

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001143
Analyte	NIC-GLUC
Sample type	URINE
Result	379
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001143
Analyte	THCOT
Sample type	URINE
Result	4590
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Day 60

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112480001143
Analyte	THCOT-GLUC
Sample type	URINE
Result	2930
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112490001605
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
--------	---

Result Unit	FG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-07
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Date of Collection	2014-MAY-27
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001627
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Analyte	1-NA
---------	------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-MAY-27
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
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Urine End Day	61
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001627
----------------	----------------

Analyte	2-NA
---------	------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-MAY-27
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001627
----------------	----------------

Analyte	4-ABP
---------	-------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-MAY-27
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Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112510001627
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Analyte	O-TOL
---------	-------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-MAY-27
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
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Urine End Day	61
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112530000510
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Analyte	11-DTXB2
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Sample type	URINE
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Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
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Celerion Study Number	AA99128-11
-----------------------	------------

Date of Collection	2014-MAY-27
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112540000503
Analyte	IPF2A-III
Sample type	URINE
Result	300
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-12
Date of Collection	2014-MAY-27
Timepoint-minutes	
Urine Start Day	60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115190003629
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99598-03
Date of Collection	2014-MAY-27
Timepoint-minutes	
Urine Start Day	60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003620
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99598-01
Date of Collection	2014-MAY-27
Timepoint-minutes	
Urine Start Day	60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115170003620
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Analyte	SPMA
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Sample type	URINE
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Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
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Celerion Study Number	AA99598-01
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Date of Collection	2014-MAY-27
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	60
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115180003629
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Analyte	MHBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-MAY-27
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	60
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05115160001605
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Analyte	CREATININE
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Sample type	URINE
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Result	.
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Result Unit	MG/DL
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
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Celerion Study Number	AA99128-14
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Date of Collection	2014-MAY-27
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Urine Start Day	60
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Urine End Day	61
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001975
Analyte	COT
Sample type	PLASMA
Result	302
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-01
Date of Collection	2014-MAY-27
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine End Day

60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Sample Barcode	05112430001975
Analyte	NIC
Sample type	PLASMA
Result	14.6
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-01
Date of Collection	2014-MAY-27
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Day 60

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:38

Generated On: 20 Jul 2016 21:53:10

Urine End Day

60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:32
----------------------	-------

Time of butt return	06:40
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	07:14
----------------------	-------

Time of butt return	07:22
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	08:35
----------------------	-------

Time of butt return	08:43
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	10:09
----------------------	-------

Time of butt return	10:18
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	11:15
----------------------	-------

Time of butt return	11:24
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:13
----------------------	-------

Time of butt return	12:20
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	14:04
----------------------	-------

Time of butt return	14:13
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	14:57
----------------------	-------

Time of butt return	15:05
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	16:20
----------------------	-------

Time of butt return	16:29
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:23
----------------------	-------

Time of butt return	17:31
---------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:08
----------------------	-------

Time of butt return	18:16
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:55
----------------------	-------

Time of butt return	19:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	19:45
----------------------	-------

Time of butt return	19:52
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	20:18
----------------------	-------

Time of butt return	20:28
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	20:30
----------------------	-------

Time of butt return	20:38
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 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	21:47
----------------------	-------

Time of butt return	21:56
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:26
----------------------	-------

Time of butt return	22:34
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:47
----------------------	-------

Time of butt return	22:55
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:20
----------------------	-------

Time of butt return	07:29
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044001
-------------------	----------------------

Comment	EVENT NOT RECORD ON HST - WAS A TEST.
---------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:53
----------------------	-------

Time of butt return	09:03
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 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	13:29
----------------------	-------

Time of butt return	13:38
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 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	15:14
----------------------	-------

Time of butt return	15:22
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 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	16:11
----------------------	-------

Time of butt return	16:18
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 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	17:42
----------------------	-------

Time of butt return	17:51
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 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	18:17
----------------------	-------

Time of butt return	18:26
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044007
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 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	19:24
----------------------	-------

Time of butt return	19:32
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044008
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:43
----------------------	-------

Time of butt return	20:50
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:24
----------------------	-------

Time of butt return	22:31
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044010
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	28 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:44
----------------------	-------

Time of butt return	22:53
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044011
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:49
----------------------	-------

Time of butt return	06:56
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044012
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 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	08:03
----------------------	-------

Time of butt return	08:10
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044013
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 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	08:44
----------------------	-------

Time of butt return	08:50
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044014
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 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	10:09
----------------------	-------

Time of butt return	10:16
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044015
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:52
----------------------	-------

Time of butt return	13:00
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044016
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 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	14:06
----------------------	-------

Time of butt return	14:14
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044017
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (36)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:30
----------------------	-------

Time of butt return	15:36
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044018
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (36)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (37)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:02
----------------------	-------

Time of butt return	18:10
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044019
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (37)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (38)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:52
----------------------	-------

Time of butt return	19:01
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044020
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (38)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (39)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 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	21:07
----------------------	-------

Time of butt return	21:15
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044021
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (39)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (40)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:05
----------------------	-------

Time of butt return	22:11
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044022
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (40)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (41)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	29 MAR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	22:38
----------------------	-------

Time of butt return	
---------------------	--

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	0257
----------------------------	------

SODIM file number	VAL10089ZRHXX1044023
-------------------	----------------------

Comment	TIME BUTT RETURNED OMITTED AT TASK
---------	---------------------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (41)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (42)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <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	09:04
----------------------	-------

Time of butt return	09:10
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (42)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (43)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <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	10:27
----------------------	-------

Time of butt return	10:36
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (43)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (44)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <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	12:00
----------------------	-------

Time of butt return	12:07
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (44)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (45)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <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	13:21
----------------------	-------

Time of butt return	13:29
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (45)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (46)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <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	14:13
----------------------	-------

Time of butt return	14:22
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
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Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (46)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (47)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <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	16:14
----------------------	-------

Time of butt return	16:24
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (47)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (48)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <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	18:21
----------------------	-------

Time of butt return	18:31
---------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (48)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (49)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <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	19:16
----------------------	-------

Time of butt return	19:27
---------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (49)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (50)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <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	21:05
----------------------	-------

Time of butt return	21:13
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (50)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (51)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:05
----------------------	-------

Time of butt return	22:12
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (51)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (52)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:16
----------------------	-------

Time of butt return	22:25
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (52)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (53)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <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	06:33
----------------------	-------

Time of butt return	06:42
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (53)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (54)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <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	12:05
----------------------	-------

Time of butt return	12:13
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (54)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (55)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <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	13:01
----------------------	-------

Time of butt return	13:09
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (55)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (56)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:47
----------------------	-------

Time of butt return	13:56
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (56)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (57)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <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	15:19
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (57)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (58)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <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	16:08
----------------------	-------

Time of butt return	16:14
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (58)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (59)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <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	18:08
----------------------	-------

Time of butt return	18:16
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (59)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (60)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:37
----------------------	-------

Time of butt return	18:43
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (60)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (61)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <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	20:53
----------------------	-------

Time of butt return	20:59
---------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (61)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (62)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:27
----------------------	-------

Time of butt return	22:34
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (62)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (63)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	31 MAR 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:44
----------------------	-------

Time of butt return	22:52
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (63)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (64)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:31
----------------------	-------

Time of butt return	06:38
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044024
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (64)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (65)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
------------------------------------	-------------

Visit	Day 4 <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	08:02
----------------------	-------

Time of butt return	08:08
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044025
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (65)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (66)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
------------------------------------	-------------

Visit	Day 4 <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	08:49
----------------------	-------

Time of butt return	08:56
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044026
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (66)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (67)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
------------------------------------	-------------

Visit	Day 4 <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	12:05
----------------------	-------

Time of butt return	12:13
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044027
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (67)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (68)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
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Visit	Day 4 <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	14:15
----------------------	-------

Time of butt return	14:23
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044028
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (68)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (69)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
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Visit	Day 4 <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	16:01
----------------------	-------

Time of butt return	16:08
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044029
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (69)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (70)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
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Visit	Day 4 <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	18:21
----------------------	-------

Time of butt return	18:30
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044030
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Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (70)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (71)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
------------------------------------	-------------

Visit	Day 4 <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	19:32
----------------------	-------

Time of butt return	19:41
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044031
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Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (71)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (72)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:04
----------------------	-------

Time of butt return	21:10
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044032
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (72)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (73)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:03
----------------------	-------

Time of butt return	22:09
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044033
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (73)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (74)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	01 APR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:30
----------------------	-------

Time of butt return	22:38
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	089
---------------------	-----

SODIM sample holder number	257
----------------------------	-----

SODIM file number	VAL10089ZRHXX1044034
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (74)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (75)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	06:33
----------------------	-------

Time of butt return	06:40
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (75)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (76)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	08:10
----------------------	-------

Time of butt return	08:16
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (76)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (77)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	10:06
----------------------	-------

Time of butt return	10:13
---------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (77)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (78)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	12:08
----------------------	-------

Time of butt return	12:18
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (78)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (79)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	13:48
----------------------	-------

Time of butt return	13:56
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (79)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (80)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	14:31
----------------------	-------

Time of butt return	14:38
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (80)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (81)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	15:37
----------------------	-------

Time of butt return	15:47
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (81)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (82)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	16:40
----------------------	-------

Time of butt return	16:49
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (82)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (83)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	17:33
----------------------	-------

Time of butt return	17:41
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (83)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (84)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	19:09
----------------------	-------

Time of butt return	19:16
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (84)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (85)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <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	21:20
----------------------	-------

Time of butt return	21:26
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (85)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (86)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	02 APR 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:13
----------------------	-------

Time of butt return	22:24
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (86)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (87)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day 6 <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	06:37
----------------------	-------

Time of butt return	06:46
---------------------	-------

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, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (87)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (88)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day 6 <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	08:11
----------------------	-------

Time of butt return	08:20
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (88)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (89)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day 6 <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	09:04
----------------------	-------

Time of butt return	09:12
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (89)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (90)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day 6 <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	10:29
----------------------	-------

Time of butt return	10:36
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (90)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (91)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 APR 2014
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Visit	Day 30 <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	<hr/>
----------------------	-------

Time of butt return	<hr/>
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	167
---------------------	-----

SODIM sample holder number	0213
----------------------------	------

SODIM file number	08DY0167COHL30213001
-------------------	----------------------

Comment	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (91)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-mCC (92)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	27 MAY 2014
------------------------------------	-------------

Visit	Day 60 <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	<hr/>
----------------------	-------

Time of butt return	<hr/>
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHL60542001
-------------------	----------------------

Comment	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-mCC (92)

Data signed: (hfarmer1) 29 Mar 2015 19:06:39

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 29 Mar 2015 19:06:54

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:54

Generated On: 20 Jul 2016 21:53:10

Date of product use DD/MMM/YYYY	26 MAR 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization please explain	PRODUCT TEST
---	--------------

Time of distribution	15:31
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
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Tobacco plug kit number	<hr/>
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Tobacco plug vial number	<hr/>
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SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:54

Generated On: 20 Jul 2016 21:53:10

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: HST 4 hours (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:54

Generated On: 20 Jul 2016 21:53:10

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Not Done	False
----------	-------

If Not Done, please specify _____

Date DD/MMM/YYYY	27 APR 2014
---------------------	-------------

SODIM device distribution time hour:min 24-hour clock	09:18
--	-------

SODIM device collection time hour:min 24-hour clock	13:18
--	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: HST 4 hours (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:54

Generated On: 20 Jul 2016 21:53:10

Visit	Day 60 <input checked="" type="radio"/>
-------	---

Not Done	False
----------	-------

If Not Done, please specify _____

Date DD/MMM/YYYY	27 MAY 2014
---------------------	-------------

SODIM device distribution time hour:min 24-hour clock	08:30
--	-------

SODIM device collection time hour:min 24-hour clock	12:30
--	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: HST 4 hours (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:54

Generated On: 20 Jul 2016 21:53:10

Visit	Day 90 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	SUBJECT EARLY TERMED FROM STUDY
-----------------------------	------------------------------------

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, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (1)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (2)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (3)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (4)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (5)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (6)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (7)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (8)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (9)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (10)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (11)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (12)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (13)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (14)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (15)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (16)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (17)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (18)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (19)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044001
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File Status	Error 
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Rejection / Error reason	NB. PUFFS < 3
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0089ZRHXX0257001_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (20)


Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044002
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257002_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (21)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044003
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0089ZRHXX0257003_1
----------------------	------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (22)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044004
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257004_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (23)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044005
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0089ZRHXX0257005_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (24)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044006
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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	09 DEC 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	VALI0089ZRHXX0257006_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (25)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044007
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257007_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (26)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044008
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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	09 DEC 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	VALI0089ZRHXX0257008_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (27)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044009
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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	09 DEC 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	VALI0089ZRHXX0257009_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (28)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044010
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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	09 DEC 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	VALI0089ZRHXX0257010_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (29)


Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044011
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257011_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (30)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044012
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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	09 DEC 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	VALI0089ZRHXX0257012_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (31)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044013
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257013_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (32)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044014
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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	09 DEC 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	VALI0089ZRHXX0257014_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (33)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044015
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257015_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (34)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044016
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257016_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (35)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044017
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0089ZRHXX0257017_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (36)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044018
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257018_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (37)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044019
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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	09 DEC 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	VALI0089ZRHXX0257019_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (38)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044020
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257020_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (39)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044021
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257021_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (40)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044022
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet <input checked="" type="radio"/>
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Comment	
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Modified File Number	VALI0089ZRHXX0257022_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (41)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044023
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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	09 DEC 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	VALI0089ZRHXX0257023_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (42)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (43)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (44)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (45)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (46)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (47)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (48)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (49)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (50)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (51)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (52)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (53)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (54)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (55)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (56)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (57)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (58)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (59)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (60)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (61)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (62)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (63)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (64)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044024
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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	09 DEC 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	VALI0089ZRHXX0257024_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (65)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044025
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257025_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (66)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044026
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257026_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (67)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044027
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257027_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (68)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044028
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	
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Modified File Number	VALI0089ZRHXX0257028_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (69)


Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044029
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257029_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (70)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044030
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257030_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (71)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044031
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257031_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (72)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044032
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257032_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (73)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044033
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257033_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (74)


Generated On: 20 Jul 2016 21:53:10

SODIM file number	VAL10089ZRHXX1044034
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	09 DEC 2014
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Operator	Anthony Bruchet 
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Comment	<hr/>
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Modified File Number	VALI0089ZRHXX0257034_1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (75)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (76)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (77)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (78)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (79)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (80)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (81)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (82)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (83)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (84)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (85)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (86)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (87)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (88)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (89)

Generated On: 20 Jul 2016 21:53:10

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (90)

Generated On: 20 Jul 2016 21:53:10

SODIM file number _____

File Status _____

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator _____

Comment _____

Modified File Number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (91)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	08DY0167COHL30213001
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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	05 SEP 2014
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Operator	Thierry Bachmann <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, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Topography files status for mCC (92)

Generated On: 20 Jul 2016 21:53:10

SODIM file number	08DY0160COHL60542001
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File Status	Error 
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Rejection / Error reason	INVERSED PIPE
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product use diary(Paper)

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used?

No ☒

Reason not done

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

Was paper questionnaire used?

No ☐

Reason not done

Date of completion
DD/MMM/YYYY

Time of completion
hh:mm

Date the questionnaire was completed for
DD/MMM/YYYY

What tobacco/nicotine product did you use today?

How many THS 2.2 tobacco sticks did you use today?

How many CC/ roll-your-own did you smoke today?

What NRT product did you used today?

How many times did you use an inhaler today?

How many times did you use a nasal spray today?

How many gums did you use today?

How many lozenges did you use today?

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

How many patches did you use today? _____

How many times did you use other NRT products today
not listed previously? _____

What other tobacco product did you used today? _____

How many times did you use chewable/smokeless
tobacco today? _____

How many cigars/cigarillos did you smoke today? _____

How many times did you smoke a pipe today? _____

How many times did you use a tobacco product today
not listed previously? _____

How many times did you use an electronic cigarette
today? _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 29 Mar 2015 19:06:54

Generated On: 20 Jul 2016 21:53:10

Was there any Adverse Event for this subject?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

AE Identifier	1
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Adverse Event	INCREASED CREATININE LEVEL
---------------	----------------------------

Start Date	28 MAR 2014
------------	-------------

DD/MMM/YYYY

End Date	30 MAR 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
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AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

AE expectedness

Action taken with study product

None ☒

Other action taken

REPEAT LABS DONE

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

AE Identifier	2
---------------	---

Adverse Event	ABRASION RIGHT HAND PALM
---------------	--------------------------

Start Date	23 MAY 2014
------------	-------------

DD/MMM/YYYY

End Date

DD/MMM/YYYY

Ongoing at final contact	Yes <input type="radio"/>
--------------------------	---------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

Action taken with study product

None ☒

Other action taken

Outcome

Unknown ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

AE Identifier	3
---------------	---

Adverse Event	DECREASED DLCO
---------------	----------------

Start Date	03 APR 2014
------------	-------------

DD/MMM/YYYY

End Date

DD/MMM/YYYY

Ongoing at final contact	Yes <input type="radio"/>
--------------------------	---------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Related <input type="radio"/>
-------------------------	-------------------------------

AE expectedness	Yes <input type="radio"/>
-----------------	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (hcoleman1) 18 Jun 2015 21:18:37

Generated On: 20 Jul 2016 21:53:10

Action taken with study product

None



Other action taken

Outcome

Not Recovered or Not
Resolved



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Has the subject taken previous or concomitant
medication?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (1)

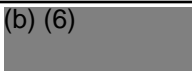
Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Unscheduled ☒

Accession ID U966811

Actual Collection Date 2014 03 30

Actual Collection Time 07:03

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Unscheduled ☒

Accession ID U966811

Actual Collection Date 2014 03 30

Actual Collection Time 07:03

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Unscheduled ☒

Accession ID U966811

Actual Collection Date 2014 03 30

Actual Collection Time 07:03

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.0
Reported Numeric Result	4.0
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

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/>
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Visit Type	Unscheduled <input checked="" type="radio"/>
------------	--

Accession ID	U966811
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	07:03
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	54
Reported Numeric Result	54
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

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	Unscheduled <input checked="" type="radio"/>
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Accession ID	U966811
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Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	07:03
------------------------	-------

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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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	LDH
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	146
Reported Numeric Result	146
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Unscheduled ☒

Accession ID U966811

Actual Collection Date 2014 03 30

Actual Collection Time 07:03

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	144
Reported Numeric Result	144
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Unscheduled ☒

Accession ID U966811

Actual Collection Date 2014 03 30

Actual Collection Time 07:03

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.8
Reported Numeric Result	4.8
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Unscheduled <input checked="" type="radio"/>
------------	--

Accession ID	U966811
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	07:03
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT29
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input type="radio"/>
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	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (9)

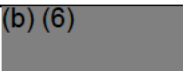
Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Unscheduled ☐

Accession ID U966811

Actual Collection Date 2014 03 30

Actual Collection Time 07:03

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	10
Reported Numeric Result	10
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

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	Unscheduled <input checked="" type="radio"/>
------------	--

Accession ID	U966811
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	07:03
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT392
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	CREATININE (RATE BLANKED)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.0
Reported Numeric Result	1.0
Reference Range low	0.5
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (11)

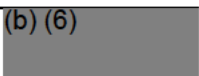
Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

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	Unscheduled <input checked="" type="radio"/>
------------	--

Accession ID	U966811
--------------	---------

Actual Collection Date	2014 03 30
------------------------	------------

Actual Collection Time	07:03
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT4
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	10
Reported Numeric Result	10
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Unscheduled ☐

Accession ID U966811

Actual Collection Date 2014 03 30

Actual Collection Time 07:03

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (13)

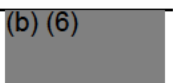
Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Unscheduled ☒

Accession ID U966811

Actual Collection Date 2014 03 30

Actual Collection Time 07:03

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	17
Reported Numeric Result	17
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1235

Folder: Unscheduled Visit >> Laboratory Assessments

Form: Clinical Chemistry

Data signed: (hfarmer1) 29 Mar 2015 19:06:55

Generated On: 20 Jul 2016 21:53:10

Date of Sample Collection
DD/MMM/YYYY

Was the subject
fasting for at
least 10 hours
at time of
sample
collection?

30 MAR 2014

Yes

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Form: Product use diary (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 04
Time of completion hh:mm	09:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 03
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?	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, Daytona Beach, Florida: 1235

Form: Product use diary (1)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Form: Product use diary (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 05
Time of completion hh:mm	12:01
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?	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, Daytona Beach, Florida: 1235

Form: Product use diary (2)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 05
Time of completion hh:mm	22:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 05
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, Daytona Beach, Florida: 1235

Form: Product use diary (3)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 06
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 06
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, Daytona Beach, Florida: 1235

Form: Product use diary (4)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 07
Time of completion hh:mm	21:01
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?	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, Daytona Beach, Florida: 1235

Form: Product use diary (5)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 08
Time of completion hh:mm	20:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 08
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?	16
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, Daytona Beach, Florida: 1235

Form: Product use diary (6)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Form: Product use diary (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 09
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 09
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, Daytona Beach,
Florida: 1235**

Form: Product use diary (7)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Form: Product use diary (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 11
Time of completion hh:mm	12:01
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?	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?	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, Daytona Beach, Florida: 1235

Form: Product use diary (8)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Form: Product use diary (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 11
Time of completion hh:mm	20:00
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?	20
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, Daytona Beach,
Florida: 1235**

Form: Product use diary (9)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Form: Product use diary (10)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 14
Time of completion hh:mm	10:01
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?	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?	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, Daytona Beach, Florida: 1235

Form: Product use diary (10)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (11)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 14
Time of completion hh:mm	20:01
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?	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, Daytona Beach, Florida: 1235

Form: Product use diary (11)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (12)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 15
Time of completion hh:mm	21:01
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?	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?	18
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, Daytona Beach, Florida: 1235

Form: Product use diary (12)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (13)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 16
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 16
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?	17
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, Daytona Beach, Florida: 1235

Form: Product use diary (13)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 18
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 18
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?	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, Daytona Beach, Florida: 1235

Form: Product use diary (14)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 20
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 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?	20
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, Daytona Beach, Florida: 1235

Form: Product use diary (15)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 21
Time of completion hh:mm	21:01
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?	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?	19
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, Daytona Beach, Florida: 1235

Form: Product use diary (16)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 22
Time of completion hh:mm	21:01
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?	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?	17
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, Daytona Beach, Florida: 1235

Form: Product use diary (17)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (18)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 23
Time of completion hh:mm	21:01
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?	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?	20
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, Daytona Beach, Florida: 1235

Form: Product use diary (18)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (19)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 24
Time of completion hh:mm	21:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 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?	18
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, Daytona Beach, Florida: 1235

Form: Product use diary (19)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (20)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 26
Time of completion hh:mm	11:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 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?	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

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Form: Product use diary (20)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (21)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 26
Time of completion hh:mm	22:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 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?	20
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, Daytona Beach, Florida: 1235

Form: Product use diary (21)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (22)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 27
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 27
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, Daytona Beach, Florida: 1235

Form: Product use diary (22)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach, Florida: 1235

Form: Product use diary (23)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 28
Time of completion hh:mm	21:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 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?	19
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, Daytona Beach, Florida: 1235

Form: Product use diary (23)

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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, Daytona Beach,
Florida: 1235**

Form: End of study

Data signed: (hcoleman1) 18 Jun 2015 21:18:36

Generated On: 20 Jul 2016 21:53:10

End of study date

25 JUN 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Lost To Follow-up ☒

Details:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1235**

Form: Consent Withdrawal

Data signed: (hfarmer1) 29 Mar 2015 19:04:40

Generated On: 20 Jul 2016 21:53:10

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
